# JOHNSON & JOHNSON

## FORM 8-K
(Current report filing)

Filed 07/20/12 for the Period Ending 07/16/12

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| Address | ONE JOHNSON & JOHNSON PLZ<br>NEW BRUNSWICK, NJ 08933 |
| Telephone | 732-524-2455 |
| CIK | 0000200406 |
| Symbol | JNJ |
| SIC Code | 2834 - Pharmaceutical Preparations |
| Industry | Biotechnology & Drugs |
| Sector | Healthcare |
| Fiscal Year | 12/12 |

**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, DC 20549**

# FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): July 16, 2012


(Exact name of registrant as specified in its charter)

| New Jersey | I-3215 | 22-1024240 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933

(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: 732-524-0400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 8.01 Other Events.**

On July 16, 2012, the United States District Court for the District of New Jersey issued an order preliminarily approving a proposed settlement by and among Johnson & Johnson, the plaintiffs, and all named individual defendants in the shareholder derivative actions entitled *In re Johnson & Johnson Derivative Litigation* , No. 10-2033; *In re Johnson & Johnson FCPA Derivative Litigation* , No. 11-02511; and *Copeland v. Prince et al.* , No. 11-04993.

A hearing to determine whether the court should issue an order of final approval of the settlement has been scheduled for September 28, 2012, at 10:00 a.m. in Courtroom 5E at the United States District Court for the District of New Jersey, Clarkson S. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, New Jersey 08608. Pursuant to the court's order, any objections to the settlement must be filed in writing with the court by no later than September 14, 2012.

Additional information concerning the terms of the proposed settlement, the September 28, 2012 hearing, and the requirements for objections can be found in the Notice of Proposed Settlement of Derivative Actions, Final Settlement Hearing and Right to Appear (the "Notice"), attached hereto as Exhibit 99.1. Also attached as Exhibit 99.2 are the Stipulation and Agreement of Settlement and Exhibits A and B thereto. This Form 8-K and the attachments are available on Johnson & Johnson's website at http://www.investor.jnj.com/investor-relations.cfm .

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Notice of Proposed Settlement of Derivative Actions, Final Settlement Hearing and Right to Appear |
| 99.2 | Stipulation and Agreement of Settlement |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**Johnson & Johnson**
(Registrant)

July 20, 2012

By: /s/ Lacey P. Elberg
Lacey P. Elberg
Assistant Secretary

Exhibit 99.1

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

| | |
|---|---|
| IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION | Civil Action No. 10-2033 (FLW) |
| IN RE JOHNSON & JOHNSON FCPA SHAREHOLDER DERIVATIVE LITIGATION | Civil Action No. 11-2511 (FLW) |
| COPELAND v. PRINCE, ET AL. | Civil Action No. 11-4993 (FLW) |

**NOTICE OF PROPOSED SETTLEMENT OF DERIVATIVE ACTIONS, FINAL SETTLEMENT HEARING, AND RIGHT TO APPEAR**

**TO: ALL HOLDERS OF JOHNSON & JOHNSON COMMON STOCK AS OF JULY 11, 2012 WHO CONTINUE TO HOLD SUCH SHARES**

**PLEASE READ THIS NOTICE CAREFULLY.**

**THE DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY**

**(THE "COURT") HAS AUTHORIZED THIS NOTICE TO BE SENT TO YOU.**

**THIS IS NOT A SOLICITATION.**

This notice (the "Notice") advises you of the proposed settlement (the "Settlement") of derivative claims brought against certain current and former directors and officers ("Individual Defendants") of Johnson & Johnson ("J&J" or the "Company") (collectively with the Individual Defendants, "Defendants"). The parties to the Derivative Actions (as defined below) have entered into a Stipulation and Agreement of Settlement (the "Stipulation"), which is subject to Court approval before becoming final. As detailed below, the parties believe that the proposed Settlement provides substantial benefits to the Company, and is in the best interests of the Company and its shareholders. If the Settlement is approved by the Court, all Released Plaintiff Claims against all of the Released Defendant Parties (as those terms are defined in the Stipulation and described in this Notice) will be dismissed with prejudice. You are provided this Notice because records indicate you are a shareholder of J&J as of July 11, 2012.

A hearing (the "Settlement Hearing") is scheduled to be held on September 28, 2012 at 10:00 a.m. before the Honorable Freda L. Wolfson, at the United States District Court for the District of New Jersey, in Courtroom 5E, Clarkson S. Fisher Building & U.S. Courthouse, 402 East State

Street, Trenton, New Jersey 08608, for the purposes of determining, among other issues, whether to: (i) finally approve the Settlement; (ii) dismiss the Derivative Actions with prejudice; and (iii) award attorneys' fees and reimbursement of expenses to Plaintiffs' Counsel (as defined in the Stipulation). This Notice summarizes the nature of the Derivative Actions, the terms of the proposed Settlement, and your rights in connection with the Settlement and the Settlement Hearing. Nothing in this Notice constitutes a finding of the Court regarding the merits of the claims or defenses asserted by any party, the merits of the Settlement, or any other matter, nor does it reflect the views of the Court.

The Defendants have denied the allegations against them and continue to deny vigorously any wrongdoing or liability with respect to all claims asserted in the Derivative Actions.

Plaintiffs believe that the proposed Settlement directly addresses significant quality control and compliance deficiencies that plaintiffs allege led to J&J's recent regulatory and legal issues in connection with the manufacturing and marketing of J&J products. Specifically, as described below, Plaintiffs believe the proposed Settlement will fundamentally improve J&J's internal reporting and oversight framework for quality control and regulatory compliance by requiring the adoption of reforms that will assure that J&J's senior management and Board of Directors (the "Board") will be informed about and will take timely and effective action to address quality and compliance related issues that could affect the value of the Company. The parties believe that the Settlement confers substantial benefits upon, and is in the best interests of J&J and its shareholders.

**YOU SHOULD READ THE NOTICE CAREFULLY BECAUSE YOUR LEGAL RIGHTS MAY BE AFFECTED.**

## I. What are the Derivative Claims About?

The Derivative claims [1] that are the subject of this Notice seek recovery on behalf of J&J based on claims of breach of fiduciary duty asserted against the Individual Defendants. [2] From April 21 through June 24, 2010, six shareholder derivative lawsuits were filed in the Court. [3] These de-

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[1] A derivative claim is a claim brought by a shareholder on behalf of a company, rather than on behalf of the shareholders of the company. The recovery sought in a derivative action is for the benefit of the company rather than directly for individual shareholders.

[2] The named Individual Defendants in the Derivative Actions are: Dominic J. Caruso, Mary Sue Coleman, James G. Cullen, Robert J. Darretta, Ian E.L. Davis, Russell C. Deyo, Michael Dormer, Seth Fischer, Colleen Goggins, Alex Gorsky, Michael M.E. Johns, Ann Dibble Jordan, Arnold G. Langbo, Ralph S. Larsen, James T. Lenehan, Susan L. Lindquist, Peter Luther, Ashley McEvoy, Robert Miller, Ann M. Mulcahy, Leo F. Mullin, William D. Perez, Christine Poon, Charles O. Prince, Steven S. Reinemund, David Satcher, Henry B. Schacht, Joseph C. Scodari, Ted Torphy, Nicholas Valeriani, William C. Weldon, and Robert N. Wilson.

[3] These actions were: (i) *Calamore v. Coleman, et al.* , Case No. 3:10-cv-02033- FLW-DEA; (ii) *Carpenters Pension Fund of West Virginia v. Weldon, et al.* , Case No. 3:10-cv-02275- FLW-DEA; (iii) *Feldman v . Coleman, et al.* , Case No. 3:10-cv-02386-FLW-DEA; (iv) *Hawaii Laborers Pension Fund v. Weldon, et al.* , Case No. 3:10-cv-02516-FLW-DEA; (v) *Ryan v. Weldon, et al.* , Case No. 3:10-cv-03147- (continued)

rivative complaints alleged that the Individual Defendants violated fiduciary duties owed to the Company by, among other things, failing to ensure that the Company complied with FDA-mandated current Good Manufacturing Practices ("cGMP"), resulting in product recalls and the closure of manufacturing facilities, failing to prevent the alleged off-label marketing of major J&J drugs, failing to prevent the alleged payment of kickbacks and bribes, and other improper activities or practices. On May 2, 2011 and May 10, 2011, two additional derivative complaints were filed in the Court, alleging that the Individual Defendants violated the fiduciary duties they owed to J&J in connection with the Company's compliance with the Foreign Corrupt Practices Act. [4]

In addition, from February through November 2010, a number of demand letters were submitted to the Board by other J&J shareholders, demanding that the Board investigate, institute litigation and take other remedial actions in connection with, among other things, alleged failures with respect to the Company's disclosures and operations related to various matters including allegations of unlawful payments to Omnicare and other entities in violation of government regulations, lack of good manufacturing practices resulting in recalls, off-label marketing and promotion activities, violations of the Foreign Corrupt Practices Act, and sales of defective products. In response to the demand letters and the derivative litigation, J&J's Board adopted resolutions appointing a Special Committee to investigate, review and analyze the shareholders' allegations and to recommend to the Board what actions, if any, should be taken. The Special Committee, with the assistance of outside counsel, conducted an extensive investigation. On June 27, 2011, the Special Committee issued the Report of the Special Committee of the Board of Johnson & Johnson (the "Report"), which was submitted to the Court. The Special Committee determined that the matters raised by the shareholders did not warrant litigation to be brought by or on behalf of J&J. However, the Special Committee recommended that the Board establish a new Regulatory and Compliance Committee responsible for oversight of the Company's Health Care Compliance and Quality and Compliance systems and issues. The independent directors unanimously approved the recommendations of the Special Committee and its counsel at the Board's July 18, 2011 meeting. On August 29, 2011, two Company shareholders who previously had served demand letters upon the Board filed additional derivative complaints in this Court, alleging that the Board had wrongfully refused their demands. [5]

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(continued...)

FLW-DEA; and (vi) *Minneapolis Firefighters' Relief Association v. Weldon et al.* , Case No. 3:10-cv-03215-FLW-DEA. The Court consolidated those cases under Case No. 10-2033. Following extensive briefing and oral argument, the Court granted Defendants' Motion to Dismiss without prejudice on September 29, 2011.

[4] Those actions were: *Wollman v. Coleman et al* ., No. 11-02511-FLW and *Cafaro v. Coleman et al.* , No. 11- 2652-FLW. The Court consolidated those cases under Case No. 11-2511. The Court consolidated those cases under Case No. 11-2511.

[5] Those actions were: *Copeland v. Prince et al.* , No. 11-04993 and *Katz v. Weldon et al.* , No. 11-04994.

Together, the derivative complaints and the demand letters discussed above are referred to in this Notice and in the Stipulation as the "Derivative Actions," and the attorneys for plaintiffs in these actions are referred to as "Plaintiffs' Counsel."

## II. What Are the Terms of the Proposed Settlement?

As detailed in the Stipulation, the governance, compliance, and risk management policies, procedures and provisions set forth in Exhibit A (the "Governance Reforms") were agreed to as a result of the Derivative Actions and as consideration for the Settlement. *See, e.g.* , Stipulation, ¶ L. In addition, based on its own evaluations and in part in response to Plaintiffs' allegations in the Derivative Actions, J&J implemented enhancements and changes as set forth in Exhibit B (the "Governance Enhancements and Changes") during the pendency of the Derivative Actions. *Id.*

The Governance Reforms at Exhibit A, combined with the Governance Enhancements and Changes set forth in Exhibit B, provide the basis for the proposed Settlement. As discussed at Section VIII below, for a comprehensive description of the terms of the proposed Settlement, please refer to Exhibit A and Exhibit B to the Stipulation, available from Plaintiffs' Counsel, the Court or J&J's corporate website. You may also request from Plaintiffs' Counsel copies of Plaintiffs' briefing in support of the settlement and the reports of Plaintiffs' experts, which further describe the provisions of the proposed Settlement and the benefits they provide to J&J and its shareholders.

At the center of the proposed Settlement is J&J's agreement to adopt governance and management reforms that will support the early identification, prevention and timely resolution of quality control and regulatory compliance issues arising throughout the lifecycle of J&J's products. As summarized below, these reforms go to the heart of Plaintiffs' allegations in the Derivative Actions. Plaintiffs believe that the proposed Settlement will place J&J at the forefront of best practices in the industry, and provide substantial benefits to the Company and its shareholders in the early detection and prevention of quality control and compliance issues.

The proposed Settlement provides for, among other things: (i) the adoption by the Board of the Q&C Core Objective; (ii) the adoption by the RCGC of the Charter and Operating Procedure set forth in Exhibit A; (iii) the adoption of the Product Risk Management Standard at J&J during 2013; (iv) making adherence to and furtherance of the Q&C Core Objective a factor in the evaluation and compensation of all J&J employees; and (v) the funding of the Governance Reforms for the five year term of the agreement. Each of these areas is discussed below.

### A. J&J's Adoption of the Quality and Compliance Core Objective

Under the terms of the proposed Settlement, the Board of J&J, by resolution, will adopt the Q&C Core Objective, pursuant to which the Company will affirm its resolve to operate its businesses, sectors, entities and franchises in compliance with applicable laws, regulations and J&J policies and standards, to deliver high quality products that patients and providers can trust, and to conduct its activities, and have policies and procedures in place so as to minimize adverse regulatory enforcement action.

The Q&C Core Objective expressly provides that the Company will design and/or maintain robust quality control and quality assurance systems to prevent, timely detect and correct noncompliance with the Quality Policy and standards within J&J. [6] To ensure that problems and issues are not permitted to remain unresolved at the operational company level, the Q&C Core Objective requires that these quality control and quality assurance systems will include tracking remediation against established timelines, and that these systems will be subject to benchmarking and metrics that will evolve to reflect successful implementation of the Q&C Core Objective. *See* Exhibit A, Section I.

The Q&C Core Objective requires that the Board's resolution will authorize the Chief Executive Officer, J&J Chief Compliance Officer ("CCO") and J&J Chief Quality Officer ("CQO") to take all appropriate and reasonable actions necessary to achieve the Q&C Objective. Under the proposed Settlement, J&J will adopt and/or maintain policies, procedures and standards to ensure the effective implementation of the Q&C Core Objective, including the design and/or maintenance of robust quality control and quality assurance systems to prevent, detect and correct noncompliance with the Quality Policy and standards with J&J, including tracking remediation against established timelines. The Q&C Core Objective also requires the Company to design and/or maintain robust systems to actively monitor for, and prevent or remedy breaches of internal J&J policies and standards and regulatory or legal compliance in the areas of quality and health care compliance. The Q&C Core Objective further requires that the Company's compliance systems will provide the resources and information necessary to review, escalate and resolve issues arising from the development and marketing of J&J products. In accordance with the Q&C Core Objective, compliance with applicable laws, regulations and internal policies, procedures and standards will be reviewed regularly throughout the life-cycle of products, including those related to the marketing and promotion of drugs and devices.

### B. Making Adherence to the Quality and Compliance Core Objective a Factor in the Evaluation and Compensation of J&J Employees

Plaintiffs believe that the adoption of the Q&C Core Objective sets a critical "tone from the top," first by requiring the adoption of the Q&C Core Objective at the Board level, and then through the adoption of provisions affecting both communication of the Q&C Core Objective throughout the enterprise and embedding the Q&C Core Objective in the evaluation and compensation systems of the Company. Following its adoption by the Board, the Q&C Core Objective will be disseminated in a Company-wide communication, with similar communications being disseminated enterprise-wide on an annual basis thereafter. *See* Exhibit A, Section II. In addition, the Q&C Core Objective will be provided to all new employees. *Id.* Finally, these communications will instruct that adherence to and furtherance of the Q&C Core Objective is to be considered in the evaluation and compensation of all J&J employees. *Id.*

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[6] In addition, the Q&C Core Objective requires that the Company will design and/or maintain robust systems to actively monitor for, and prevent or remedy breaches of internal J&J policies and standards and regulatory or legal compliance in the areas of quality and health care compliance.

This last requirement is of particular importance in Plaintiffs' opinion. Plaintiffs believe that one of the most effective ways to ensure directives from the top are embraced and adhered to below is to tie individual employee compensation to compliance with such directives, and to tie the compensation of management to the successful implementation of such directives throughout their functional areas of responsibility.

### C. Adoption of the RCGC Charter and Operating Procedure

Pursuant to the proposed Settlement, J&J has agreed that the RCGC will adopt the Charter and the Operating Procedure (the "C/OP") set forth at Exhibit A, which provide for oversight responsibility at the RCGC for all aspects of non-financial quality control and regulatory compliance at J&J. The C/OP require robust and regular reporting from relevant management areas at the Company, including the J&J CCO, the J&J CQO, and the Vice President Corporate Internal Audit ("V.P. CIA"), to support and track the effective implementation and operation of regulatory compliance and compliance and quality programs and systems. The C/OP places responsibility in the RCGC to oversee the adequacy of funding of the compliance and quality functions, which Plaintiffs believe will provide an important safeguard against any pressure to underfund these areas. The C/OP also places responsibility on the RCGC itself to assess the adequacy of the information it is receiving to support its oversight functions set forth in the C/OP. Key components of the C/OP are summarized below. For a complete description of the obligations and responsibilities placed on the RCGC and management under the C/OP, please see Exhibit A, Sections III.A. and B. in their entirety.

**1. C/OP Reporting Provisions.** The Operating Procedure sets out the scope and timing of reporting to the RCGC by, among others, the J&J CQO, J&J CCO, V.P. Supply Chain, and V.P. CIA. Specific to such reporting responsibilities, the Charter requires both quarterly and annual reporting, including regarding the organization, implementation and effectiveness of the Company's compliance programs (for the CCO), and quality and compliance programs (for the CQO), as well as the adequacy of the resources for these programs, including relevant compliance, and quality and compliance programs at newly acquired companies. *See* Charter, "Duties and Responsibilities of the Committee," ¶¶ 3 and 4. In addition, at least annually, the CQO is also required to report on such matters as the adequacy of resource allocation to the Company's quality systems and operations and strategic goals and objectives of the CQO organization **.** *Id.*

The Operating Procedure also requires reporting from the V.P. Supply Chain [7] - including annual reporting regarding supply chain risk management issues, and from the V.P. CIA - including quarterly reporting regarding the implementation of the annual audit plan in relevant areas, along with any material findings, and at least annual reporting regarding the adequacy of resources for the annual audit plan in relevant areas. *See* Operating Procedure, ¶¶ 3.c.and d. In addition, the Charter expressly provides that the RCGC must at least annually review and approve the Company's internal audit plans related to compliance and quality. *See* Charter, "Duties and Responsibilities of the Committee," ¶ 11.

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[7] At J&J, the CQO reports to the Vice President Supply Chain ("V.P. Supply Chain").

The Operating Procedure also requires reporting to the RCGC "concerning medical safety and related quality issues, which will include a review of quality and safety issues impacting each Sector, presented by the respective Sector Chief Medical Officer and Sector Safety Medical Officer (or equivalent)." Operating Procedure, ¶ 3.e.

Recognizing that issues may arise that require reporting to the RCGC even more promptly than on a quarterly basis, the Settlement provides for interim reporting by the CCO, CQO, V.P. Supply Chain and V.P. CIA directly to the Chair of the RCGC regarding substantial matters. *See* Operating Procedure, ¶ 3.a., b., c. and d.

**2. Oversight of ERM Effectiveness.** The Operating Procedure requires the RCGC at least biennially to consider the effectiveness of, and recommend changes to, the enterprise risk management ("ERM") program at J&J for those ERM areas under the Committee's purview, and to report any recommended changed to the full Board. *See* Operating Procedure, ¶ 4.

**3. Open Access to the RCGC.** Combined with their detailed required reporting obligations under the proposed Settlement, the C/OP also provide that the CCO, CQO and V.P. CIA will have direct access to the Committee and its Chairman (Operating Procedure, ¶ 6), and that the RCGC will hold separate private meetings at lease semi-annually with these officers, among others. *See* Charter, "Meetings of the Committee," ¶ 2.

**4. Other Oversight Responsibilities.** In addition to the reporting with respect to the implementation and operation of the compliance and quality systems, the Operating Procedure requires the CCO, CQO and V.P. Supply Chain each independently to report on trends affecting the Company in his or her respective area, and, "as appropriate, plans of action to respond to such trends from a preventive standpoint." *See* Operating Procedure, ¶¶ 3. a., b. and d. In addition, the Charter provides that the RCGC shall oversee the Company's exposure to risk relating to regulatory compliance, Health Care Compliance & Privacy and Quality & Compliance matters, and shall review and evaluate new developments and current and emerging trends relating to regulatory compliance, quality and government relations that affect or could affect the Company. *See* Charter, "Duties and Responsibilities of the Committee," ¶¶ 10 and 13. Plaintiffs believe that by addressing regulatory and risk-related trends as they develop or arise, J&J will be better positioned to act proactively to avoid problems and issues which those trends may signal going forward.

**D. Adoption of the Product Risk Management Standard**

As discussed above, the proposed Settlement also provides for the design and implementation of a Product Risk Management Standard at J&J. The Settlement describes this requirement as follows:

J&J will design and implement a Product Risk Management ("PRM") Standard under the Quality Policy and the Quality Framework. The PRM Standard will address the overall quality process for appropriate reporting, escalation, and

remediation of issues arising with products (as defined in the Quality Policy). The PRM Standard will address the following topics, among others: responsibility for development of action plans; parameters for development of and adoption of resolution timelines; documentation requirements; and quality metrics for evaluating issue resolution, including tracking remediation against established timelines. The PRM Standard will set forth the independence and role of Quality personnel in the PRM process, and will provide that all quality issues subject to the PRM Standard will be managed in accordance with the escalation reporting line defined in the Quality Policy. The PRM Standard will be a mandatory standard applicable across the J&J Enterprise. Compliance with the PRM Standard will be subject to oversight by the independent Enterprise Regulatory Compliance Group and by the J&J Quality organization. The CQO will be responsible for ensuring the design and adoption of appropriate Sector Standards and SOPs, as necessary, to implement the Enterprise PRM Standard. The PRM Standard will be implemented during 2013.

*See* Exhibit A, Section IV.A.

Plaintiffs believe that the PRM Standard will be an important tool in the Company's compliance with requirements of the Q&C Core Objective, particularly those aspects directed to the timely detection, correction and prevention of issues and activities that could result in problems at J&J.

Plaintiffs further believe that it is significant that J&J has agreed to implement the PRM Standard during 2013, because this undertaking will require leadership at the highest reaches of the Company, a significant commitment of financial resources, and, taken together with other provisions of the proposed Settlement, shows a commitment by J&J to significant reform going forward.

**E. Settlement Commitment Term and Funding Provisions**

The Company has agreed to maintain the provisions of the settlement as set forth in Exhibits A and B, for a period of not less than five years from the Effective Date of the Settlement. This period is defined in the Stipulation as the "Settlement Commitment Term." *See* Stipulation, ¶ 2.3. Plaintiffs believe that the five years is a substantial period of time to permit these reforms to become part of the J&J culture going forward.

In addition, the Company has agreed that for the Settlement Commitment Term it will spend such funds as are necessary to implement and maintain the Exhibit A and B provisions, and that the CQO or CCO have discretion to make funding recommendations directly to the Board or an appropriate committee of the Board." *Id.* , ¶ 2.2. The funding commitments ensure the levels of funding necessary to effectively implement the reforms to which J&J has committed. The ability of the CQO and the CCO to directly seek Board intervention in funding determinations significantly strengthens their ability to ensure the streams of funding necessary to fully implement these reforms.

**III. What Are the Reasons for the Settlement?**

The parties believe that the Settlement, as set forth in the Stipulation and Exhibits A and B attached thereto, confers substantial benefits upon J&J and its shareholders. The Settlement has been achieved after significant investigation and analysis by Plaintiffs' Counsel, including review of internal documents produced by the Company. The detailed provisions of the Settlement reflect the results of intensive negotiations between the parties, undertaken with the benefit of discussions involving J&J's Chief Quality Officer, Plaintiffs' Counsel and pharmaceutical industry experts retained on behalf of plaintiffs.

As reflected in the Stipulation, the parties agree that the Settlement provides substantial benefits to J&J and its shareholders , including supporting the detection and prevention of the types of underlying issues alleged in the Derivative Actions. In recommending that the parties settle at this time under the terms and conditions set forth in the Settlement, Plaintiffs' Counsel have weighed the risks of further litigation against the substantial benefits that counsel were able to obtain for J&J and its shareholders pursuant to the Settlement.

The Defendants have denied and continue to deny that they have any liability as a result of any or all of the allegations asserted in the Derivative Actions or that they engaged in any wrongdoing whatsoever. J&J and the Individual Defendants are entering into the settlement to undertake the changes in corporate governance to benefit J&J and its shareholders, and to eliminate the burden, distraction, expenses and uncertainty of further litigation.

**IV. What Attorneys' Fees And Reimbursement of Expenses Will Be Sought?**

Under the terms of the Settlement, Plaintiffs' Counsel will request not more than $10,000,000 for their fees and $450,000 for reimbursement of their expenses, subject to Court approval. J&J will not oppose such a fee and expense request. Plaintiffs' Counsel have been retained by their clients on a contingent fee basis and, thus, to date Plaintiffs' Counsel have not been paid for their legal services or reimbursed for expenses they have incurred in connection with the litigation of the Derivative Actions. The expenses are primarily comprised of expert fees Plaintiffs' Counsel incurred in their retention of corporate governance and pharmaceutical industry experts who provided substantial assistance to Plaintiffs' Counsel in connection with the litigation and settlement of the Derivative Actions.

The attorneys' fees and award of expenses for which Plaintiffs' Counsel will seek Court approval were the subject of arm's-length negotiations among the parties, begun only after the terms of the proposed Settlement were agreed upon.

**V. What Will Happen at the Settlement Hearing** ?

The Court has scheduled a Settlement Hearing for September 28, 2012 at 10:00 a.m. At this hearing, the Court will hear any objections to any aspect of the Settlement raised by any J&J shareholder who held shares of J&J common stock as of July 11, 2012 and continues to hold such shares as of the date of the Settlement Hearing (“Current J&J Shareholder”). At or following the hearing, the Court will determine whether the Settlement is fair, reasonable, and adequate, and determine whether to enter a final order approving the Settlement. The Court will

also consider the Plaintiffs' Counsel's application for attorneys' fees and reimbursement of expenses. Pending final determination of whether the Settlement should be approved, Plaintiffs and all other J&J shareholders are barred and enjoined from instituting or prosecuting any action that asserts any of the Released Plaintiff Claims against any Released Parties (as those terms are described below and defined in the Stipulation).

**YOU ARE NOT REQUIRED TO PARTICIPATE IN OR ATTEND THE SETTLEMENT HEARING, BUT MAY DO SO IF YOU WISH.** If you are a Current J&J Shareholder, and you wish to express an objection to any portion of the Settlement or Plaintiffs' Counsel's application for attorneys' fees and reimbursement of expenses, you must send a signed letter or other signed written submission providing a detailed statement of your specific objections. Your written objection must (i) state your name, address, and telephone number, (ii) provide the number of shares of J&J common stock you owned as of July 11, 2012 and that you currently own as of the date of the submission, accompanied by copies of brokerage statement(s) evidencing such ownership of J&J common stock, and (iii) provide a detailed description of your specific objections to any matter before the Court, all the grounds for your objections, and any documents you wish the Court to consider. You must mail the objection and your supporting papers to the Court and each of the attorneys listed at the addresses provided below to arrive no later than September 14, 2012. YOUR OBJECTION MUST BE IN WRITING AND RECEIVED BY THIS DATE TO BE CONSIDERED. If your objection is not received in a timely manner, the Court may deem it waived and may not consider it.

**Court:**

Clerk of the Court
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608,

**Plaintiffs' Counsel:**

Carella, Byrne, Cecchi, Olstein,
Brody & Agnello, P.C.
Attn: James E. Cecchi
5 Becker Farm Road
Roseland, NJ 07068

Kantrowitz, Goldhamer &
Graifman, P.C.
Attn: Gary Graifman
210 Summit Avenue
Montvale, NJ 07645

**Defendants' Counsel:**

Patterson Belknap Webb & Tyler
Attn: Erik Haas
1133 Avenue of the Americas
New York, NY 10036

Sidley Austin LLP
Attn: Kristen R. Seeger
One South Dearborn Street
Chicago, IL 60603

The Court will consider your written objection whether or not you choose to attend the Settlement Hearing. You may also choose to retain your own lawyer at your own expense to represent you with respect to any objections you may have. If you or your lawyer would like to speak at the Settlement Hearing, you must send a letter stating that you intend to appear and speak at the Settlement Hearing. The letter must include the name(s) of your attorney(s) and any witness(es) you may call to testify and must identify any documents you intend to introduce into evidence at the Settlement Hearing. The letter must also include (i) your name, address, and telephone number, and (ii) how many shares of J&J common stock you owned as of July 11, 2012 and that you currently own as of the date of the submission, accompanied by copies of brokerage statement evidencing such ownership of J&J common stock. Your letter must be received no later than September 14, 2012 by the Clerk of the Court, Plaintiffs' Counsel, and Defendants' Counsel, at the addresses provided above. The date of the Settlement Hearing is subject to change without further notice to J&J shareholders. If you or your lawyer intend to attend the Settlement Hearing, you should confirm the date and time with Plaintiffs' Counsel.

## VI. What Is the Effect of the Court's Approval of the Settlement?

If the Settlement is approved, the Court will enter a Final Order and Judgment. The Final Order and Judgment (the "Judgment") will dismiss the Derivative Actions with prejudice, and pursuant to the Judgment, upon the Effective Date of the Settlement, Plaintiffs and each and every other J&J shareholder, on behalf of themselves, their heirs, executors, administrators, predecessors, successors and assigns, will be deemed by operation of law to have fully, finally and forever released, waived, discharged, and dismissed each and every Released Plaintiff Claim (as defined below), and will forever be enjoined from prosecuting any and all Released Plaintiff Claims, against any and all Released Defendant Parties (as defined below). Further, pursuant to the Judgment, upon the Effective Date of the Settlement, each of the Defendants and each of the other Released Defendant Parties, on behalf of themselves, their heirs, executors, administrators, predecessors, successors and assigns, will be deemed by operation of law to have fully, finally, and forever released, waived, discharged, and dismissed each and every Released Defendant Claim (as defined below), and will forever be enjoined from prosecuting any and all Released Defendant Claims, against any and all Released Plaintiff Parties (as defined below). For the purposes of this Settlement:

(a) "Released Plaintiff Claims" means any and all claims, demands, rights, actions, potential actions, causes of action, liabilities, damages, losses, obligations, judgments, duties, suits,

agreements, costs, expenses, debts, interest, penalties, sanctions, fees, attorneys' fees, judgments, decrees, matters, issues, and controversies of any kind, nature or description whatsoever, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether fixed or contingent, accrued or un-accrued, liquidated or un-liquidated, at law or in equity, matured or un-matured, disclosed or un-disclosed, apparent or un-apparent, including claims and Unknown Claims (as defined below), which were or could have been alleged or asserted in the Derivative Actions against any Released Defendant Party by Plaintiffs or any other J&J shareholder derivatively on behalf of J&J, directly or indirectly relating to or arising out of any of the allegations, facts, events, transactions, acts, occurrences, conduct, practices, or any other matters, or any series thereof, alleged or asserted in the Derivative Actions, or which were investigated by the Special Committee. Released Plaintiff Claims do not include any claims relating to the enforcement of this settlement. Released Plaintiff Claims also do not include the specific claims made by the plaintiff in *The George Leon Family Trust v. Coleman, et al.* , Case No. 3:11-cv-05084-JAP-DEA.

(b) "Released Plaintiffs Parties" means Plaintiffs and all other J&J shareholders and their respective Related Parties.

(c) "Released Defendant Claims" means any and all claims, demands, rights, actions, potential actions, causes of action, liabilities, damages, losses, obligations, judgments, duties, suits, agreements, costs, expenses, debts, interest, penalties, sanctions, fees, attorneys' fees, judgments, decrees, matters, issues, and controversies of any kind, nature or description whatsoever, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether fixed or contingent, accrued or un-accrued, liquidated or un-liquidated, at law or in equity, matured or un-matured, disclosed or un-disclosed, apparent or un-apparent, including claims and Unknown Claims (as defined below), which were or could have been alleged or asserted by any of the Released Defendant Parties against any of the Released Plaintiff Parties, directly or indirectly relating to or arising out of the institution, prosecution, or settlement of the Derivative Actions. Released Defendant Claims do not include any claims relating to the enforcement of this Settlement.

(d) "Released Defendant Parties" means all Defendants and their Related Parties.

(e) "Related Parties" means the respective past, present, or future family members, spouses, heirs, trusts, trustees, executors, estates, administrators, beneficiaries, foundations, agents, employees, parents, subsidiaries, divisions, affiliates, officers, managers, directors, predecessors, predecessors-in-interest, successors, successors-in-interest, assigns, advisors, consultants, attorneys, personal or legal representatives, accountants, auditors, insurers, co-insurers, reinsurers and associates of any Defendant or J&J shareholder, as well as any entity in which any Defendant or J&J shareholder has a controlling interest, or any trust of which any Defendant or J&J shareholder is the settlor or which is for the benefit of any Defendant or J&J shareholder and/or member(s) of his or its family.

(f) "Unknown Claims" means any Released Plaintiff Claims that J&J, Plaintiffs, or any other J&J shareholder does not know or suspect to exist in his, her, or its favor at the time of the release of the Released Defendant Parties, and any Released Defendant Claims that any Defendant

or any other Released Defendant Party does not know or suspect to exist in his, her, or its favor at the time of the release of the Released Plaintiff Parties, which if known by him, her, or it, might have affected his, her, or its decision not to object to this settlement. With respect to any and all Released Plaintiff Claims and Released Defendant Claims, the Settling Parties stipulate and agree that upon the Effective Date, Plaintiffs, the Company, and each of the Individual Defendants shall expressly waive, and each other J&J shareholder and each other Released Defendants Party expressly be deemed to have waived, and by operation of the Judgment shall have expressly waived, any and all provisions, rights, and benefits conferred by Cal. Civ. Code § 1542, which provides:

> A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor; and shall have expressly waived any and all similar provisions, rights, and benefits conferred by any similar statute.

Plaintiffs, J&J, and each of the Individual Defendants acknowledge, and each other J&J shareholder and each other Released Defendant Party by operation of law shall be deemed to have acknowledged, that the inclusion of "Unknown Claims" in the definition of Released Plaintiff Claims and Released Defendant Claims was separately bargained for and was a key element of the settlement.

Neither the settlement nor any act performed or document executed pursuant to or in furtherance of the settlement or the negotiation thereof, including this Notice, is or may be deemed to be an admission or, or evidence of, any fault, liability, or omission of any of the Individual Defendants or the Released Defendant Parties in any proceeding of any kind or nature.

## VII. Special Notice to Securities Brokers and Other Nominees

Brokerage firms, banks, and/or other persons or entities that hold shares of the common stock of J&J as of July 11, 2012 for the benefit of others are directed promptly to send this Notice to all of their respective beneficial owners. If additional copies of the Notice are needed for forwarding to such beneficial owners, any requests for such copies may be made to:

Sidley Austin LLP
Attn: Kristen R. Seeger
One South Dearborn Street
Chicago, IL 60603

## VIII. How Do You Get More Information about the Derivative Actions and the Proposed Settlement?

The foregoing description of the lawsuit, the terms of the proposed settlement, the Settlement Hearing, and other matters described herein is only a summary. For the full details of the lawsuit and the terms and conditions of the Stipulation, J&J's shareholders are referred to the text of the Stipulation and Exhibits (which may be found on J&J's website at http://www.investor.jnj.com/investor-relations.cfm ), the Court's orders referred to herein, and to

the pleadings and other papers filed and to be filed with the Court. The papers filed with the Court may be examined during regular business hours at the Office of the Clerk of the Court, United States District Court for the District of New Jersey, Clarkson S. Fisher Building & U.S. Courthouse, 402 East State Street, Trenton, New Jersey 08608.

**Please do not contact the Court for information or telephone the Court or Clerk's Office regarding this Notice.** Any questions regarding this Notice or the proposed Settlement, or requests to obtain copies of settlement-related documents, including copies of the papers to be submitted in support of final approval of the Settlement and the application for attorneys' fees and reimbursement of expenses, may be directed to the following Plaintiffs' Counsel:

Carella, Byrne, Cecchi, Olstein,
Brody & Agnello, P.C.
Attn: James E. Cecchi
5 Becker Farm Road
Roseland, NJ 07068

Kantrowitz, Goldhamer &
Graifman, P.C.
Attn: Gary Graifman
210 Summit Avenue
Montvale, NJ 07645

DATE: July 16, 2012

Exhibit 99.2

**UNITED STATES DISTRICT COURT**

**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION | Civil Action No. 10-2033 (FLW) |
| IN RE JOHNSON & JOHNSON FCPA SHAREHOLDER DERIVATIVE LITIGATION | Civil Action No. 11-2511 (FLW) |
| COPELAND v. PRINCE, ET AL. | Civil Action No. 11-4993 (FLW) |

**STIPULATION AND AGREEMENT OF SETTLEMENT**

This Stipulation and Agreement of Settlement, dated July 11, 2012 (the "Stipulation"), is entered into between and among the Settling Parties (as defined below), and is intended to fully, finally and forever compromise, resolve, discharge and settle the Released Claims (as defined below) in accordance with the terms and conditions set forth below, subject to the approval of the United States District Court for the District of New Jersey (the "Court") pursuant to Rule 23.1 of the Federal Rules of Civil Procedure.

**HISTORY OF THE LITIGATION**

A. The Derivative Actions (as defined herein) are shareholder derivative actions brought for the benefit of nominal defendant Johnson & Johnson ("J&J" or the "Company") (as defined below) against the Individual Defendants (as defined below, and together with J&J, the "Settling Defendants").

B. The Derivative Actions allege broadly that from the late 1990s until 2011, the Individual Defendants breached their fiduciary duties to the Company and its shareholders, *inter alia* , in connection with the manufacturing, production, distribution and marketing of various

medical and consumer products and devices, as set forth in the complaints filed in the above-captioned actions as well as in shareholder demand letters sent to the Company's Board of Directors.

C The Derivative Actions include demand letters (the "Demand Letters") sent by shareholders to the Company's Board of Directors (the "Board"), actions in which Plaintiffs allege pursuant to Fed. R. Civ. P. 23.1(b)(3)(B) that it would have been futile to demand that the Board investigate and pursue litigation against the Individual Defendants (the "Demand Futile Actions"), and actions wherein Plaintiffs allege pursuant to Fed. R. Civ. P. 23.1(b)(3)(A) that the Board wrongfully refused demands that were made on the Board (the "Demand Refused Actions"). The Demand Letters, the Demand Futile Actions, and the Demand Refused Actions, collectively, are referred to herein as the "Derivative Actions."

Demand Letters, Special Committee Process, and Demand Refused Actions

D. From February through November 2010, a number of Demand Letters were submitted to the Board, demanding that the Board investigate, institute litigation and take other remedial actions in connection with alleged failures with respect to the Company's disclosures and operations related to various alleged matters including, *inter alia* , unlawful payments to Omnicare and other entities in violation of government regulations, lack of good manufacturing practices resulting in recalls, off-label marketing and promotion activities, violations of the Foreign Corrupt Practices Act, and sales of defective products. [1] On April 22, 2010, in response to the Demand Letters received as of that date, the Board adopted a resolution appointing a

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[1] The following shareholders made demands upon the J&J Board from February through November 2010: Leslie Katz, Jeffrey Tarson, and Joan Tarson (February 17, 2010 and July 7, 2010); the New Jersey Building Laborers Annuity & New Jersey Building Laborers Pension Funds (March 23, 2010); Glenn Bassett (April 15, 2010); Howard Lipschutz (May 11, 2010); Martha Copeland (May 20, 2010); Dan Miran (May 26, 2010); S.L. Lerner (June 17, 2010); and Michael Waber (Nov. 12, 2010).

Special Committee to investigate, review and analyze the allegations made in the Demand Letters, and to recommend to the Board what actions, if any, should be taken. The Board resolution also granted the Special Committee authority to retain legal counsel to assist with its investigation. Pursuant to this authority, the Special Committee retained Douglas S. Eakeley of the law firm Lowenstein Sandler P.C. as counsel to the Special Committee. On June 15, 2010, in response to additional Demand Letters and the allegations in the Demand Futile Actions, the Board expanded the authority of the Special Committee to investigate, review, and analyze the additional allegations made.

E. The Special Committee conducted an extensive investigation. On June 27, 2011, the Special Committee issued the Report of the Special Committee of the Board of Johnson & Johnson (the "Report"), which was submitted to the Court. (Dkt. Entry No. 149 in Case No. 10-2033, Attachment 1.) The Special Committee determined that the matters raised in the Demand Letters and Demand Futile Actions did not warrant litigation to be brought by or on behalf of J&J. However, the Special Committee recommended that the Board establish a new Regulatory and Compliance Committee responsible for oversight of the Company's Health Care Compliance and Quality and Compliance systems and issues. The independent directors unanimously approved the recommendations of the Special Committee and its counsel at the Board's July 18, 2011 meeting.

F. On August 29, 2011, two Company shareholders who previously had served Demand Letters upon the Board filed derivative complaints in this Court, alleging that the Board had wrongfully refused the Demand Letters. [2] Following a motion for consolidation and appointment of lead counsel, the Court consolidated the cases under Case No. 11-04993 and

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[2] See *Copeland v. Prince et al.* , No. 11-04993 (D.N.J.) and *Katz v. Weldon et al.* , No. 11-04994 (D.N.J.).

named Abraham, Fruchter, & Twersky, LLP as Lead Counsel and Kantrowitz, Goldhamer & Graifman, P.C. as Liaison Counsel for the Demand Refused Actions by order dated November 21, 2011. Pursuant to the settlement discussions, the parties have agreed to extend the dates for the Defendants to answer or otherwise respond to the Demand Refused Actions.

Demand Futile Actions

G. From April 21 through June 24, 2010, six Demand Futile Actions were filed in the Court, alleging that the Individual Defendants violated fiduciary duties owed to the Company by, *inter alia* , failing to ensure that the Company complied with FDA-mandated cGMP, and failing to prevent alleged off-label marketing, kickbacks, bribes and other improper activities or practices. [3]

H. On August 17, 2010, the Court ordered the consolidation of the Demand Futile Actions under the caption *In re Johnson & Johnson Derivative Litigation* , No. 10-2033-FLW (the "Consolidated Action") and appointed the law firms of Bernstein Litowitz Berger & Grossmann LLP; Morris and Morris LLC Counselors At Law; Carella Byrne, Cecchi, Olstein, Brody & Agnello, P.C.; and Robbins Geller Rudman & Dowd LLP as Co-Lead Counsel for the Demand Futile Actions, with the sole authority, *inter alia* , to determine and present to the Court and opposing parties the positions of the Plaintiffs on all matters arising during pretrial proceedings and conduct settlement negotiations on behalf of Plaintiffs related to the Demand Futile Actions.

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[3] These actions were: (i) *Calamore v. Coleman, et al.* , Case No. 3:10-cv-02033- FLW-DEA, filed April 21, 2010; (ii) *Carpenters Pension Fund of West Virginia v. Weldon, et al.* , Case No. 3:10-cv-02275- FLW-DEA, filed May 5, 2010; (iii) *Feldman v . Coleman, et al.* , Case No. 3:10-cv-02386-FLW-DEA, filed May 6, 2010; (iv) *Hawaii Laborers Pension Fund v. Weldon, et al.* , Case No. 3:10-cv-02516-FLW-DEA, filed May 14, 2010; (v) *Ryan v. Weldon, et al.* , Case No. 3:10-cv-03147-FLW-DEA, filed June 18, 2010; and (vi) *Minneapolis Firefighters' Relief Association v. Weldon et al.* , Case No. 3:10-cv-03215-FLW-DEA filed June 24, 2010.

I. Defendants moved to dismiss the Demand Futile Consolidated Amended Complaint on February 21, 2011. Following extensive briefing and oral argument on July 28, 2011, by order dated September 29, 2011, the Court granted Defendants' Motion to Dismiss without prejudice. The time for the Demand Futile Plaintiffs to determine whether they intend to file an amended complaint, pursue a demand for production of books and records, or take any other action has been extended by the Court while the parties engaged in the negotiations leading to this Stipulation.

J. On May 2, 2011 and May 10, 2011, two additional Demand Futile actions were filed in the Court, alleging that the Individual Defendants violated the fiduciary duties they owed to the Company in connection with the Company's compliance with the FCPA. [4] The Court consolidated these cases under Case No. 11-2511. Co-Lead Counsel in the Consolidated Action, Robbins Geller Rudman & Dowd LLP, is plaintiffs' counsel in Case No. 11-2511. Following the Defendants' filing of motions to dismiss the consolidated complaint in Case. No. 11-2511, the parties agreed to defer further proceedings on those motions while the parties engaged in the negotiations leading to this Stipulation.

K. Other demand futile actions were filed in the Superior Court of New Jersey. [5] These actions have been either voluntarily stayed or stayed as duplicative of the prior-filed federal actions.

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[4] See *Wollman v. Coleman et al* ., No. 11-02511-FLW (D.N.J.) and *Cafaro v. Coleman et al.* , No. 11- 2652-FLW (D.N.J.).

[5] See *Wolin v. Weldon et al.* , No. C-188-10 (Sup. Ct. N.J.), alleging essentially identical claims as *In re Johnson & Johnson Derivative Litigation* ; and *Clark v. Coleman et al.* , No. C-116-11 (Sup. Ct. N.J.) and *King v. Coleman et al.*, No. C-159-11 (Sup. Ct. N.J.) (consolidated under *In re Johnson & Johnson Shareholder Derivative Litigation* , No. C-116-11 (Sup. Ct. N.J.)), alleging substantially identical claims as *In re Johnson & Johnson FCPA Shareholder Derivative Litigation* .

**THE SETTLEMENT PROCESS**

L. As detailed below, as a result of the Derivative Actions and as consideration for the Settlement, J&J will agree to implement and adopt the governance, internal control, risk management and compliance provisions set forth at Exhibit A hereto (the "Governance Reforms"). Moreover, during the pendency of and in part in response to the Derivative Actions, J&J implemented enhancements and changes as set forth in Exhibit B hereto (the "Governance Enhancements and Changes").

M. Following the oral argument but prior to the Court ruling on the motions to dismiss the Demand Futile Actions, and following the submission made to the Court by Demand Refused Counsel with respect to the Special Committee Report, Plaintiffs' Counsel and Defendants' Counsel commenced settlement negotiations. Lead Demand Futile Counsel engaged as their consultants Harvey Pitt, former Chairman of the Securities and Exchange Commission, and Dr. Mitchell Glass, an experienced former pharmaceutical industry executive, to propose corporate governance, health care compliance, and quality control reforms. Working with their experts, Lead Demand Futile Counsel designed and presented a series of detailed settlement proposals directed at both the Board and management levels. The Company carefully reviewed these proposals and negotiated extensively with Lead Demand Futile Counsel for seven months with respect to them.

N. Demand Refused Counsel engaged as their consultants Dr. Robert Israel, an experienced physician and pharmaceutical executive, to propose corporate governance, health care compliance, and quality control reforms, and Dr. Paul Higham, an experienced medical device industry executive, including experience in the areas of commercial development and FDA approval of orthopedic implants. Working with their experts, Demand Refused Counsel

designed and presented settlement proposals directed at both the Board and management levels. Demand Refused Counsel also requested and obtained from the Company certain documents with respect to the allegations underlying the Demand Refused Action. The Company carefully reviewed these proposals and requests, and negotiated extensively with Demand Refused Counsel with respect to them.

O. The Settling Parties engaged in dialogue regarding relevant policies and procedures in place at the Company, and how the Company could effectively achieve the goals of the proposed reforms. This dialogue consisted of telephone conversations and numerous face-to-face meetings among counsel, including in-house counsel for J&J, as well as Drs. Glass and Israel and J&J's Chief Quality Officer.

P. During the course of the settlement process, the Company made a series of productions of documents relevant to corporate governance and the compliance structure and policies within the J&J organization, including improvements that have been implemented by the Company. These documents were reviewed in detail by Plaintiffs' Counsel and their experts and assisted in the negotiation of the Settlement terms.

Q. Plaintiffs' Counsel conducted an investigation into the underlying facts and merits of the Derivative Claims. This investigation began in advance of serving the Derivative Actions and Demand Letters, and continued, with the assistance of their experts, through to the settlement of the Derivative Claims. The investigation included (i) independent factual and legal analysis, (ii) the review and evaluation of the Special Committee findings, (iii) the review of the documents produced by the Company, as described above, (iv) discussions with Company representatives, (v) review of court filings including trial transcripts and exhibits from other related actions, (vi) review of publicly available information including news reports and

securities' analyst reports, and (vii) consulting with their experts. Plaintiffs' Counsel's investigation was integral to their assessment of the Derivative Claims, and their conclusion that the terms and conditions of this Stipulation confer substantial benefits upon, and are in the best interests of, the Company and its shareholders.

**THE DERIVATIVE CLAIMS AND THE BENEFITS OF SETTLEMENT**

R. Based on their review and analysis of the relevant facts, allegations, defenses, and controlling legal principles, the Settling Parties believe that the Settlement set forth herein confers substantial benefits upon, and is in the best interests of, J&J and its shareholders. The Settling Parties have agreed to settle pursuant to the terms and provisions of this Stipulation after considering, *inter alia* , the substantial benefits that J&J and its shareholders will receive if the

Settlement is approved.

S. Although Plaintiffs' Counsel (and their respective clients) believe that the Derivative Claims have substantial merit, they recognize and acknowledge the expense and length of time that would be required to prosecute the Derivative Claims through preliminary motions, trial and appeal. Plaintiffs' Counsel have also taken into account the substantial improvements that J&J has implemented, the additional agreements that J&J will undertake pursuant to this Settlement, the uncertain outcome and the risks of litigating the Derivative Claims, as well as the difficulties and delays inherent in such litigation. It is the view of Plaintiffs' Counsel that the Governance Reforms achieved in the present proposed Settlement are comprehensive and far-reaching.

T. Defendants have denied and continue to deny the Derivative Claims and all allegations of any wrongdoing or liability arising from any conduct, statements, acts or omissions alleged, or that could have been alleged, in the Derivative Actions. Defendants also

have denied and continue to deny all allegations that the Company has suffered damage by or as a result of the matters alleged in the Derivative Actions. This Stipulation and all related documents are not, and shall not in any event be construed or deemed to be evidence of fault or liability or wrongdoing or damage whatsoever, or any infirmity in Defendants' defenses. Nonetheless, Defendants have concluded that further conduct of this litigation would be time-consuming and distracting, including without limitation, to the Company and its management, and that it is desirable that these Derivative Claims be fully and finally settled upon the terms and conditions set forth in this Stipulation.

U. The Settling Parties acknowledge that the Derivative Claims have been filed, commenced and prosecuted by the Plaintiffs and defended by the Settling Defendants in good faith and with adequate basis in fact and law under Federal Rule of Civil Procedure 11, and that the Derivative Claims are being voluntarily released and settled based on the advice of counsel.

V. Plaintiffs and the Settling Defendants acknowledge and agree that the Governance Reforms set forth in Exhibit A provide a substantial benefit to the Company and its shareholders, including in the promotion of the achievement of the Quality and Compliance Core Objective, and in the prevention of potential violations of law, regulation and Company policy. Plaintiffs and the Settling Defendants further acknowledge and agree that the Governance Enhancements and Changes set forth in Exhibit B provide a substantial benefit to the Company and its shareholders, including providing a framework for enterprise-wide compliance, quality and risk management standards at J&J. As consideration for the proposed Settlement, J&J further agrees to fund and to maintain in place the Governance Reforms and the Governance Enhancements and Changes for the Settlement Commitment Term (defined below).

**NOW THEREFORE,** without any admission or concession on the part of Plaintiffs of any lack of merit of the Derivative Claims whatsoever, and without any admission or concession on the part of the Settling Defendants as to the merits of the Derivative Claims or as to any liability or wrongdoing whatsoever,

**IT IS STIPULATED AND AGREED** , by and among the Settling Parties, through their respective counsel, that, subject to the approval of the Court pursuant to Rule 23.1 of the Federal Rules of Civil Procedure, in consideration of the mutual agreements and benefits flowing to the Settling Parties from the Settlement set forth herein, the Released Claims shall be finally and fully compromised, settled and released, and the Derivative Claims shall be dismissed with prejudice, upon and subject to the following terms and conditions:

**1. DEFINITIONS**

As used in this Stipulation, the following terms shall have the following meanings:

1.1. "Alternative Judgment" means a form of final judgment that may be entered by the Court herein but in a form other than the form of Judgment provided for in this Stipulation.

1.2. "Defendants" means the Individual Defendants and nominal defendant J&J.

1.3. "Defendants' Counsel" means the law firm of Sidley Austin LLP on behalf of nominal defendant Johnson & Johnson and the law firm of Patterson Belknap Webb & Tyler on behalf of the Individual Defendants.

1.4. "Demand Refused Counsel" means Lead Demand Refused Counsel and Liaison Demand Refused Counsel.

1.5. "Derivative Actions" means the demand letters (the "Demand Letters") sent by shareholders to the Board, the actions wherein Plaintiffs allege that it would have been futile to demand that the Board investigate and pursue litigation against the Individual Defendants (the

"Demand Futile Actions"), and the actions wherein Plaintiffs allege that the Board wrongfully refused demands that were made on the Board (the "Demand Refused Actions").

1.6. "Derivative Claims" means the claims asserted in or encompassed by the Derivative Actions.

1.7. "Effective Date" means the first date by which all of the conditions and events specified in paragraph 6.1 of this Stipulation have been met and have occurred.

1.8. "Final," with respect to any judgment, including the Judgment or, if applicable, the Alternative Judgment means the latest of: (a) the expiration of the time for the filing or noticing of any motion for reconsideration or appeal of the judgment; (b) the final affirmance of the judgment on appeal or after reconsideration, the expiration of the time for a petition, or a denial of any petition, to review the affirmance of the judgment on appeal, or, if such a petition is granted, the final affirmance of the judgment following review pursuant to that grant; or (c) the final dismissal of any appeal from the judgment or the final resolution of any proceeding to review any appeal from the judgment without any material change to the judgment. Any proceeding or order, or any appeal or petition for a review of a proceeding or order, pertaining solely to any application for or award of attorneys' fees or expenses shall not in any way delay or preclude the judgment from becoming Final.

1.9. "Individual Defendants" means Dominic J. Caruso, Mary Sue Coleman, James G. Cullen, Robert J. Darretta, Ian E.L. Davis, Russell C. Deyo, Michael Dormer, Seth Fischer, Colleen Goggins, Alex Gorsky, Michael M.E. Johns, Ann Dibble Jordan, Arnold G. Langbo, Ralph S. Larsen, James T. Lenehan, Susan L. Lindquist, Peter Luther, Ashley McEvoy, Robert Miller, Ann M. Mulcahy, Leo F. Mullin, William D. Perez, Christine Poon, Charles O. Prince, Steven S. Reinemund, David Satcher, Henry B. Schacht, Joseph C. Scodari, Ted Torphy,

Nicholas Valeriani, William C. Weldon, and Robert N. Wilson.

1.10. "Johnson & Johnson" or "J&J" or "the Company" means Johnson & Johnson and any of its subsidiaries, divisions, and affiliates, and any of their predecessors or successors.

1.11. "Judgment" means the Final Order and Judgment entered by the Court in a form substantially similar to the Proposed Final Order and Judgment attached hereto as Exhibit F.

1.12. "Lead Demand Futile Counsel" means the law firms of Bernstein Litowitz Berger & Grossmann LLP; Morris and Morris LLC Counselors At Law; Carella, Byrne, Cecchi, Olstein, Brody & Agnello, P.C.; and Robbins Geller Rudman & Dowd LLP.

1.13. "Lead Demand Refused Counsel" means the law firm of Abraham, Fruchter &Twersky, LLP.

1.14. "Liaison Demand Refused Counsel" means the law firm of Kantrowitz, Goldhamer & Graifman, P.C.

1.15. "Plaintiffs" means, collectively, the plaintiffs in Civil Action Nos. 10-2033, 11-2511, and 11-4993: Minneapolis Firefighters' Relief Association, the Hawaii Laborers Pension Fund, Jeanne M. Calamore, Sandra Wollman, Gila Heimowitz, Joseph Cafaro, Cynthia Diamond, Leslie Katz, Carpenters Pension Fund of West Virginia, M.J. Copeland, Albert L. Feldman, the Investment Committee of the NECA-IBEW Pension Trust Fund, the Investment Committee of the NECA-IBEW Welfare Trust Fund, and Walter E. Ryan.

1.16. "Plaintiffs' Counsel" means, collectively, Lead Demand Futile Counsel and Demand Refused Counsel.

1.17. "Preliminary Approval Order" means the order entered by the Court in a form substantially similar to the Proposed Preliminary Approval Order attached hereto as Exhibit C.

1.18. "Related Parties" means the respective past, present, or future family members, spouses, heirs, trusts, trustees, executors, estates, administrators, beneficiaries, foundations, agents, employees, parents, subsidiaries, divisions, affiliates, officers, managers, directors, predecessors, predecessors-in-interest, successors, successors-in-interest, assigns, advisors, consultants, attorneys, personal or legal representatives, accountants, auditors, insurers, co-insurers, reinsurers and associates of any Defendant or J&J shareholder, as well as any entity in which any Defendant or J&J shareholder has a controlling interest, or any trust of which any Defendant or J&J shareholder is the settlor or which is for the benefit of any Defendant or J&J shareholder and/or member(s) of his or its family.

1.19. "Released Claims" means, collectively, the Released Defendant Claims and the Released Plaintiff Claims.

1.20. "Released Defendant Claims" means any and all claims, demands, rights, actions, potential actions, causes of action, liabilities, damages, losses, obligations, judgments, duties, suits, agreements, costs, expenses, debts, interest, penalties, sanctions, fees, attorneys' fees, judgments, decrees, matters, issues, and controversies of any kind, nature or description whatsoever, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether fixed or contingent, accrued or un-accrued, liquidated or un-liquidated, at law or in equity, matured or un-matured, disclosed or un-disclosed, apparent or un-apparent, including claims and Unknown Claims (as defined below), which were or could have been alleged or asserted by any of the Released Defendant Parties against any of the Released Plaintiff Parties, directly or indirectly relating to or arising out of the institution, prosecution, or settlement of the Derivative Actions. Released Defendant Claims do not include any claims relating to the enforcement of this Settlement.

1.21. "Released Defendant Parties" means all Defendants and their Related Parties.

1.22. "Released Plaintiff Claims" means any and all claims, demands, rights, actions, potential actions, causes of action, liabilities, damages, losses, obligations, judgments, duties, suits, agreements, costs, expenses, debts, interest, penalties, sanctions, fees, attorneys' fees, judgments, decrees, matters, issues, and controversies of any kind, nature or description whatsoever, whether based on federal, state, local, statutory or common law or any other law, rule or regulation, whether fixed or contingent, accrued or un-accrued, liquidated or un-liquidated, at law or in equity, matured or un-matured, disclosed or un-disclosed, apparent or un-apparent, including claims and Unknown Claims (as defined below), which were or could have been alleged or asserted in the Derivative Actions against any Released Defendant Party by Plaintiffs or any other J&J shareholder derivatively on behalf of J&J, directly or indirectly relating to or arising out of any of the allegations, facts, events, transactions, acts, occurrences, conduct, practices, or any other matters, or any series thereof, alleged or asserted in the Derivative Actions, or which were investigated by the Special Committee. Released Plaintiff Claims do not include any claims relating to the enforcement of this Settlement. Released Plaintiff Claims also do not include the specific claims made by the plaintiff in *The George Leon Family Trust v. Coleman, et al.* , Case No. 3:11-cv-05084-JAP-DEA.

1.23. "Released Plaintiff Parties" means Plaintiffs and all other J&J shareholders and their respective Related Parties.

1.24. "Settlement" means the agreement made and entered into by and among the Settling Parties and set forth in this Stipulation.

1.25. "Settlement Hearing" means the hearing the Settling Parties will request that the Court hold after dissemination of the Settlement Notice in order to consider and determine,

among other things, whether the Settlement should be approved; whether a final Judgment should be entered approving the Settlement, providing for the release of the Released Claims in accordance this Stipulation and dismissing the Derivative Actions with prejudice; and whether and in what amount attorneys' fees and expenses should be awarded.

1.26. “Settlement Notice” means the notice of the Settlement to be published pursuant to the Stipulation and the Preliminary Approval Order. The Settlement Notice will include: (i) filing a Form 8-K regarding the proposed Settlement, which shall include as attachments a copy of the Notice of the Proposed Settlement (substantially in the form attached hereto as Exhibit D), the Stipulation of Settlement, and Exhibits A and B (with exhibits, the “Form 8-K”); (ii) posting on J&J's corporate website copies of the Stipulation of Settlement, Exhibits A and B and the Notice of the Proposed Settlement; (iii) publishing the Summary Notice of the Proposed Settlement (substantially in the form attached hereto as Exhibit E), once each in the national edition of *The Wall Street Journal* and *USA Today* and over *PR Newswire* ; and (iv) mailing the Notice of the Proposed Settlement to those shareholders who are registered shareholders of J&J as of the date this Stipulation is signed.

1.27. “Settling Parties” means the Settling Defendants and all Plaintiffs.

1.28. “Unknown Claims” means any Released Plaintiff Claims that J&J, Plaintiffs, or any other J&J shareholder does not know or suspect to exist in his, her, or its favor at the time of the release of the Released Defendant Parties, and any Released Defendant Claims that any Defendant or any other Released Defendant Party does not know or suspect to exist in his, her, or its favor at the time of the release of the Released Plaintiff Parties, which if known by him, her, or it, might have affected his, her, or its decision not to object to this Settlement. With respect to

any and all Released Plaintiff Claims and Released Defendant Claims, the Settling Parties stipulate and agree that upon the Effective Date, Plaintiffs, the Company, and each of the Individual Defendants shall expressly waive, and each other J&J shareholder and each other Released Defendants Party expressly be deemed to have waived, and by operation of the Judgment shall have expressly waived, any and all provisions, rights, and benefits conferred by Cal. Civ. Code § 1542, which provides:

> A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor; and shall have expressly waived any and all similar provisions, rights, and benefits conferred by any similar statute.

Plaintiffs, J&J, and each of the Individual Defendants acknowledge, and each other J&J shareholder and each other Released Defendant Party by operation of law shall be deemed to have acknowledged, that the inclusion of "Unknown Claims" in the definition of Released Plaintiff Claims and Released Defendant Claims was separately bargained for and was a key element of the Settlement.

**2. SETTLEMENT OF THE DERIVATIVE ACTIONS**

In settlement of the Derivative Claims, the Settling Defendants agree, subject to the Court entering the Judgment approving the Settlement, to cause the Company to implement and/or maintain the following corporate governance measures and enhancements to compliance protocols and procedures:

2.1. Corporate Governance and Compliance Reforms . As a result of the Derivative Actions and as consideration for the Settlement, J&J and the Individual Defendants agree to implement and adopt the Governance Reforms set forth in Exhibit A. During the pendency of

and in part in response to the Derivative Actions, J&J implemented the Governance Enhancements and Changes set forth in Exhibit B.

2.2. Funding . The Company agrees that for the Settlement Commitment Term it will spend such funds as are necessary to implement and maintain the provisions set forth in Exhibits A and B attached hereto. In addition, during the Settlement Commitment Term, the J&J Chief Quality Officer or J&J Chief Compliance Officer have discretion to make funding recommendations directly to the Board or an appropriate committee of the Board.

2.3. Settlement Commitment Term . The Company agrees to maintain the provisions of the Settlement, including all of the provisions set forth in Exhibits A and B hereto, for a period of not less than five years from the Effective Date of the Settlement (the "Settlement Commitment Term").

**3. APPROVAL PROCESS**

3.1. Promptly following the execution of the Stipulation, the Settling Parties shall submit to the Court this Stipulation together with the referenced exhibits, and shall jointly apply for entry of a Preliminary Approval Order, substantially in the form of Exhibit C attached hereto, that: (a) preliminarily approves the Settlement set forth in this Stipulation; (b) sets a date for the Settlement Hearing; (c) approves the form and content of the Settlement Notice; and (d) preliminarily enjoins J&J, Plaintiffs and any other J&J shareholder from commencing, instituting, or prosecuting any of the Released Plaintiff Claims against the Released Defendant Parties and preliminarily enjoins Defendants and each of the other Released Defendant Parties from commencing, instituting or prosecuting any of the Released Defendant Claims against the Released Plaintiff Parties.

3.2. Not later than five (5) business days following entry of the Preliminary Approval

Order J&J: (i) shall cause the Form 8-K to be filed with the SEC; (ii) shall post copies of the Stipulation of Settlement, Exhibits A and B and the Notice of the Proposed Settlement on its corporate website; and (iii) shall mail the Notice of the Proposed Settlement to registered shareholders. Not later than ten (10) days following entry of the Preliminary Approval Order, J&J shall cause the Summary Notice to be published once each in the national edition of *The Wall Street Journal* and *USA Today* and over *PR Newswire* .

3.3. The Company shall be responsible for paying all costs incurred in connection with the dissemination of the Settlement Notice, whether or not the Settlement becomes effective, and in no event shall Plaintiffs, their counsel or agents be responsible for any such notice costs.

3.4. The Settling Parties shall jointly request that, after notice of the Settlement is made and the time for objection is past, the Court hold a Settlement Hearing to consider and determine: (a) whether to approve the Settlement; (b) whether Judgment should be entered dismissing the Derivative Actions with prejudice, each party to bear his, her or its own costs except as otherwise provided herein; (c) whether permanently to bar and enjoin J&J, Plaintiffs and each of the other J&J shareholders from litigating any of the Released Plaintiff Claims against any of the Released Defendants Parties and whether permanently to bar and enjoin Defendants and each of the other Released Defendant Parties from litigating any of the Released Defendant Claims against any of the Released Plaintiff Parties; and (d) whether to approve the application of Plaintiffs' Counsel for an award of fees and reimbursement of expenses.

3.5. If the Settlement contemplated by this Stipulation is approved by the Court, the Settling Parties shall jointly request that the Court enter the Judgment, substantially in the form attached hereto as Exhibit F.

**4. RELEASES OF CLAIMS**

4.1. Pursuant to the Judgment, upon the Effective Date, J&J, Plaintiffs, and each and every other J&J shareholder, on behalf of themselves, their heirs, executors, administrators, predecessors, successors and assigns, shall be deemed by operation of law to have fully, finally, and forever released, waived, discharged, and dismissed each and every Released Plaintiff Claim, and shall forever be enjoined from prosecuting any and all Released Plaintiff Claims, against any and all Released Defendant Parties.

4.2. Pursuant to the Judgment, upon the Effective Date, each of the Defendants and each of the other Released Defendant Parties, on behalf of themselves, their heirs, executors, administrators, predecessors, successors and assigns, shall be deemed by operation of law to have fully, finally, and forever released, waived, discharged, and dismissed each and every Released Defendant Claim, and shall forever be enjoined from prosecuting any and all Released Defendant Claims, against any and all Released Plaintiff Parties.

**5. ATTORNEYS' FEES AND EXPENSES**

5.1. After agreeing to the settlement consideration set forth in Section 2 above, Plaintiffs' Counsel and Defendants' Counsel negotiated the amount of attorneys' fees and expenses (“the Fee and Expense Amount”) that, subject to Court approval, would be paid to Plaintiffs' Counsel. As a result of the negotiations, the Company has agreed to pay, or cause to be paid, to Plaintiffs' Counsel not more than $10,000,000 for their fees and $450,000 for their expenses, subject to Court approval, which the Company and Defendants agree not to oppose or cause any other person to oppose.

5.2. Pursuant to the Court-approved Fee and Expense Amount, and provided that Plaintiffs' Counsel have provided to counsel for the Company the required IRS Forms and all

necessary wire transfer instructions, the Company shall pay or shall cause to be paid the Fee and Expense Amount in the amounts awarded by the Court within ten (10) business days after the Court executes an order approving the Fee and Expense Amount, notwithstanding the existence of any timely filed objections thereto, or the potential for appeal therefrom, or collateral attack on the Settlement or any part thereof. Plaintiffs' Counsel agree that acceptance of payment of the Fee and Expense Amount is subject to their obligation (including the obligations of any other person or counsel who is allocated any portion of the Fee and Expense Amount) to make repayment in full with interest computed based on the 30 Day Treasury Rate to the Company within ten (10) business days after receiving from counsel for the Company or a court of appropriate jurisdiction notice of the termination of the Settlement or notice that the Fee and Expense Amount is reduced or reversed for any reason. Plaintiffs' Counsel agree that they remain subject to the continuing jurisdiction of the Court for the purpose of enforcing their obligation to repay attorneys' fees and expenses as provided in this paragraph.

5.3. The Fee and Expense Amount is not a necessary term of this Stipulation and is not a condition of this Stipulation.

5.4. Neither Plaintiffs nor Plaintiffs' Counsel may cancel or terminate the Stipulation or the Settlement based on this Court's or any appellate court's ruling with respect to any Fee and Expense Amount.

5.5. The Released Defendant Parties shall have no responsibility for or liability with respect to the allocation of the Fee and Expense Amount among Plaintiffs' Counsel and/or any other person or counsel who may assert some claim thereto. The Released Defendant Parties shall have no responsibility or liability for any other fees or expenses claimed by any other person or counsel in connection with the matters being settled by this Stipulation. The Released

Defendant Parties shall take no position with respect to how any Fee and Expense Amount should be otherwise allocated.

**6. CONDITIONS OF SETTLEMENT, EFFECT OF DISAPPROVAL, CANCELLATION OR TERMINATION**

6.1. The Effective Date of the Settlement shall be conditioned on the occurrence or waiver of all of the following events:

(a) entry of the Preliminary Approval Order, which shall be in all material respects substantially in the form set forth in Exhibit C attached hereto;

(b) approval by the Court of the Settlement, as prescribed by Rule 23.1 of the Federal Rules of Civil Procedure; and

(c) the Judgment, which shall be in all material respects substantially in the form set forth in Exhibit F attached hereto, has been entered by the Court and has become Final or, in the event that the Court enters an Alternative Judgment and none of the Settling Parties elects to terminate this Settlement, the date that such Alternative Judgment becomes Final.

6.2. The Company, the Individual Defendants, and Plaintiffs shall, respectively, have the right to terminate the Settlement and this Stipulation by providing written notice of their election to do so ("Termination Notice"), through counsel, to all other Settling Parties hereto within thirty (30) calendar days of: (a) the Court's final refusal to enter in any material respect the Preliminary Approval Order attached hereto as Exhibit C; (b) the Court's final refusal to approve this Stipulation or any part of it that materially affects any Settling Party's rights or obligations hereunder; (c) the Court's final refusal to enter in any material respect the Judgment attached hereto as Exhibit F; (d) the date upon which the Judgment attached hereto as Exhibit F is modified or reversed in any material respect on appeal or by writ; or (e) the date upon which an Alternative Judgment is modified or reversed in any material respect on appeal or by writ.

However, any decision with respect to the award of any Fee and Expense Amount shall not be considered material to the Settlement, shall not affect the finality of the Judgment or Alternative Judgment, and shall not be grounds for termination or cancellation of the Settlement.

6.3. Except as otherwise provided herein, in the event the Settlement is terminated or the Effective Date cannot occur for any reason, then: (a) the Settlement shall be without prejudice, and none of its terms shall be effective or enforceable except as specifically provided herein; (b) the Settling Parties shall be deemed to have reverted to their respective positions in the Derivative Actions immediately prior to the execution of this Stipulation; and, (c) except as otherwise expressly provided, the Settling Parties shall proceed in all respects as if this Stipulation and any related orders had not been entered. In such event, the fact and terms of this Stipulation, and any aspect of the negotiations leading to this Stipulation, shall not be admissible in the Derivative Actions and shall not be admitted or used by Plaintiffs against the Defendants or by the Defendants against Plaintiffs in any court filings, depositions, at trial, or otherwise, and any judgments or orders entered by the Court in accordance with the terms of the Stipulation shall be treated as vacated *nunc pro tunc* .

**7. NO ADMISSION OF WRONGDOING**

7.1. Neither this Stipulation, whether or not approved by the Court, nor any of its terms or provisions, nor any document or exhibit referred or attached to this Stipulation, nor any negotiations, proceedings or agreements relating to it or actions taken to effectuate it shall be offered or received against any of the Settling Parties as evidence of or construed as or deemed to be evidence of: (a) any liability, negligence, fault, or wrongdoing of any of the Settling Parties; (b) a presumption, concession, or admission with respect to any liability, negligence, fault, or wrongdoing, or in any way referred to for any other reason as against any of the Settling

Parties, in any other civil, criminal, or administrative action or proceeding, other than such proceedings as may be necessary to effectuate the provisions of this Stipulation; (c) a presumption, concession, or admission by any of the Settling Defendants with respect to the truth of any fact alleged in the Derivative Actions or the validity of any of the claims or the deficiency of any defense that was or could have been asserted in the Derivative Actions; (d) a presumption, concession, or admission by the Plaintiffs of any infirmity in the claims asserted; or (e) an admission or concession that the consideration to be given hereunder represents the consideration which could be or would have been recovered at trial.

7.2. Neither this Stipulation nor the attached Exhibits shall be offered or received into evidence in any action or proceeding in any court or other tribunal for any purpose whatsoever other than (a) to effect or obtain Court approval for this Stipulation, (b) to enforce the terms of this Stipulation, or (c) for purposes of defending, on the grounds of *res judicata* , collateral estoppel, release, or any other theory of claim preclusion or issue preclusion or similar defense or counterclaim, any of the Released Claims released pursuant to this Stipulation.

**8. MISCELLANEOUS PROVISIONS**

8.1. Nothing herein shall expand the liabilities of any J&J director or officer beyond any liabilities otherwise imposed by law.

8.2. All of the Exhibits to this Stipulation are material and integral parts hereof and are fully incorporated by reference as though fully set forth herein.

8.3. The Settling Parties intend this Settlement to be a final and complete resolution of all disputes among themselves with respect to the Derivative Claims. The Settlement compromises claims that are contested and shall not be deemed an admission by any Settling

Party as to the merits of any claim, demand, or defense. While the Settling Defendants deny that the claims and contentions advanced in the Derivative Actions are meritorious, the Settling Defendants agree that the Derivative Claims were filed in good faith and are being settled voluntarily after negotiating at arm's-length and in good faith after consultation with experienced legal counsel. The Settling Parties agree not to assert in any forum that the Derivative Claims were brought, commenced or prosecuted by Plaintiffs or defended by the Settling Defendants in bad faith. The Settling Parties shall not assert any violation of Rule 11 of the Federal Rules of Civil Procedure relating to the prosecution, defense, or settlement of the Derivative Actions.

8.4. The Settling Parties agree that the terms of this Settlement, including the Fee and Expense Amount, were negotiated at arm's-length and in good faith by the Settling Parties, and reflect a settlement that was reached voluntarily after consultation with experienced legal counsel.

8.5. This Stipulation may not be modified or amended, nor may any of its provisions be waived, except by a writing signed by or on behalf of all signatories hereto or their successors-in interest.

8.6. The headings herein except in Exhibits A and B hereto are used for the purpose of convenience only and are not meant to have legal effect.

8.7. Without affecting the finality of the Judgment entered in accordance with this Stipulation, the Court shall retain jurisdiction with respect to the implementation and enforcement of the terms of this Stipulation, and the Settling Parties hereto submit to the jurisdiction of the Court for purposes of implementing and enforcing the Settlement embodied in this Stipulation.

8.8. The waiver by any Settling Party of any breach of this Stipulation by any other

Settling Party shall not be deemed or construed as a waiver of any other prior or subsequent reach of this Stipulation.

8.9. This Stipulation and its Exhibits constitute the entire agreement among the Settling Parties concerning this Settlement, and no representations, warranties, or inducements have been made by any party hereto concerning this Stipulation and its Exhibits other than those contained and memorialized in such documents.

8.10. This Stipulation may be executed in one or more counterparts, including by signature transmitted via facsimile or by a .pdf or .tif image of the signature transmitted via electronic mail. All executed counterparts and each of them shall be deemed to be one and the same instrument.

8.11. This Stipulation shall be binding upon, and inure to the benefit of, the Settling Parties and their respective heirs, executors, administrators, successors and assigns.

8.12. The construction, interpretation, validity and enforcement of this Stipulation, and all documents necessary to effectuate it, shall be governed by the internal laws of the State of

New Jersey without regard to conflicts of laws or choice of law rules, except to the extent that federal law requires that federal law govern.

8.13. This Stipulation shall not be construed more strictly against one Settling Party than another merely by virtue of the fact that it, or any part of it, may have been prepared by counsel for one of the Settling Parties, it being recognized that this Stipulation is the result of arm's-length negotiations between the Settling Parties and all Settling Parties have contributed substantially and materially to the preparation of this Stipulation.

8.14. All counsel and any other person executing this Stipulation and any of the exhibits hereto, or any related Settlement documents, warrant and represent that they have the

full authority to do so and that they have the authority to take appropriate action required or permitted to be taken pursuant to the Stipulation to effectuate its terms.

8.15. The Settling Parties: (a) acknowledge that it is their intent to consummate the terms and conditions of this Stipulation; and (b) agree to cooperate fully with one another to the extent reasonably necessary to effectuate and implement all terms and conditions of this Stipulation, to exercise their best efforts to accomplish the foregoing terms and conditions of this Stipulation, and to obtain Court approval of the Preliminary Approval Order, the Stipulation and this Settlement, and to execute all such other documentation as may be reasonably required to obtain final approval by the Court of the Settlement.

8.16. If any Settling Party is required to give notice to any other Settling Party under this Stipulation, such notice shall be in writing and shall be deemed to have been duly given upon receipt of e-mail, facsimile transmission with confirmation of receipt, hand delivery or overnight mail. Notice shall be provided as follows:

If to Lead Demand Futile Counsel:

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If to Demand Refused Counsel:

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If to Plaintiffs in Civil No. 3:11-cv-2511:

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If to the Company:

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**IN WITNESS WHEREOF** , the Settling Parties have caused this Stipulation to be executed by their duly authorized counsel.

DATED: July 11, 2012

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*Counsel for Johnson & Johnson*

**EXHIBIT A**

**GOVERNANCE REFORMS**

I. **Adoption of the Quality and Compliance Core Objective.**

The Board of Directors of Johnson & Johnson (the "Board") will adopt a resolution establishing the Quality and Compliance Core Objective for Johnson & Johnson. Johnson & Johnson will affirm its resolve to operate its businesses, sectors, entities and franchises:

- in compliance with applicable laws, regulations and Johnson & Johnson policies and standards;
- to deliver high quality products that patients and providers can trust;
- to conduct its activities and have policies and procedures in place so as to minimize adverse regulatory enforcement action; and
- to maintain, enhance and support effective quality and health care compliance systems designed to timely detect, correct and prevent activities violative of applicable laws, regulations and/or Company policies and standards.

(the "Quality and Compliance Core Objective"). Such resolution shall authorize the Chief Executive Officer, the Chief Compliance Officer, and the Chief Quality Officer at Johnson & Johnson to take all appropriate and reasonable actions necessary to achieve the Quality and Compliance Core Objective.

Johnson & Johnson will adopt and/or maintain policies, procedures and standards to ensure the effective implementation of the Quality and Compliance Core Objective. The Company will design and/or maintain robust quality control and quality assurance systems to prevent, detect and correct noncompliance with the Quality Policy and standards within Johnson & Johnson, including tracking remediation against established timelines. These quality systems will be subject to benchmarking and metrics that will evolve to reflect successful implementation of the Core Objective. The Company will design and/or maintain robust systems to actively monitor for, and prevent or remedy breaches of internal J&J policies and standards and

regulatory or legal compliance in the areas of quality and health care compliance. The Company's compliance systems will provide the resources and information necessary to review, escalate and resolve issues arising from the development or marketing of Johnson & Johnson products. Compliance with applicable laws, regulations, and internal policies, procedures and standards will be reviewed regularly throughout the life-cycle of products, including those related to the marketing and promotion of drugs and devices.

II. **Dissemination of the Quality & Compliance Core Objective Enterprise-Wide.**

Following its adoption by the Board, the Quality & Compliance Core Objective will be disseminated in a Johnson & Johnson-wide communication. That communication will instruct that adherence to and furtherance of the Quality & Compliance Core Objective is to be considered in the evaluation and compensation of all Johnson & Johnson employees. A similar communication will be disseminated enterprise-wide on an annual basis thereafter, and the Quality & Compliance Core Objective will be provided to new employees.

III. **Regulatory, Compliance & Government Affairs Committee, Charter and Procedures.**

The Board already has created a standing Regulatory, Compliance and Government Affairs Committee (the “Committee”) to review and monitor the implementation and effectiveness of the Company's compliance and quality programs. The Committee will operate in accordance with the following provisions:

A. **Regulatory, Compliance & Government Affairs Committee Charter**

**Purpose of the Committee**

The Regulatory, Compliance & Government Affairs Committee (the “Committee”) shall report to and assist the Board of Directors (“Board”) by providing oversight of regulatory, compliance, quality, and governmental affairs matters that may impact the Company and such other matters

as directed by the Board or this Charter. The Quality & Compliance Core Objective will inform the Committee's work.

**Membership of the Committee**

1. The Committee shall be comprised of not less than three members of the Board.

2. All members of the Committee shall be independent directors, as independence is defined in accordance with the rules, regulations and standards of the New York Stock Exchange and the Company's Standards of Independence for the Board of Directors of Johnson & Johnson, and as determined in the business judgment of the Board.

3. At least one member of the Committee shall serve concurrently on the Audit Committee.

4. Members of the Committee shall be appointed and may be removed by resolution of a majority of the non-employee directors of the Board.

5. Members of the Committee shall be informed, or shall become informed within a reasonable period of time after appointment to the Committee, with respect to matters of legal and regulatory compliance that are within the Committee's oversight responsibilities and the Company's Health Care Compliance & Privacy (HCC&P) and Quality & Compliance (Q&C) programs and policies.

**Meetings of the Committee**

1. The Committee will meet at least four times each year and will report to the Board following each such Committee meeting. The Committee will hold at least two executive sessions each year without members of management present.

2. The Committee will hold separate private meetings at least semi-annually with each of the General Counsel, the Chief Compliance Officer, the Chief Quality Officer, and the Vice President of Corporate Internal Audit.

**Duties and Responsibilities of the Committee**

Among its duties and responsibilities, the Committee shall:

1. Oversee the Company's major compliance programs with respect to regulatory requirements (including, but not limited to, the Company's policies and procedures for monitoring health care compliance, including HCC&P programs and policies; product quality and compliance, including Q&C programs and policies; product safety; privacy; environmental regulation; employee health and safety; and compliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended), except with respect to matters of financial compliance (i.e., accounting, auditing and financial reporting), which are the responsibility of the Audit Committee.

2. Oversee compliance with any ongoing Corporate Integrity Agreements or similar significant undertakings by the Company with the U.S. Department of Health and Human Services, U.S. Department of Justice, U.S. Securities and Exchange Commission, U.S. Food and Drug Administration, or any other government agency.

3. At least annually, review with the Chief Compliance Officer the organization, implementation and effectiveness of the Company's compliance programs, and the adequacy of the resources for those programs, including the compliance programs of newly acquired companies.

4. At least annually, review with the Chief Quality Officer the organization, implementation and effectiveness of the Company's quality and compliance programs, and the adequacy of the resources for those programs, including the quality and compliance programs of newly acquired companies.

5. Review the metrics used by management to provide insight into the Company's compliance and quality systems and organizations.

6. Oversee the Company's Policy on Business Conduct and Code of Business Conduct & Ethics for Members of the Board of Directors and Executive Officers, including the annual certification processes, and the procedures for identifying and investigating any alleged violation of such Policy or Code. The Vice President of Corporate Internal Audit shall at least annually report to the Committee on significant actual and alleged violations of such Policy or Code, including any such matters that involve criminal conduct or potential criminal conduct.

7. Oversee significant complaints and other matters raised through the Company's compliance reporting mechanisms (other than those involving accounting, auditing, and financial reporting, which are the responsibility of the Audit Committee).

8. At least annually, review the Company's government affairs strategies and priorities.

9. At least annually, review the policies, practices and priorities for the Company's political expenditure and lobbying activities.

10. Oversee the Company's exposure to risks relating to regulatory compliance, HCC&P, and Q&C matters.

11. At least annually, review and approve the Company's internal audit plans related to compliance and quality.

12. Consult with the Compensation and Benefits Committee of the Board regarding the application of the Quality and Compliance Core Objective in employee performance evaluations and compensation.

13. Review and evaluate new developments and current and emerging trends relating to regulatory compliance, quality, and government relations that affect or could affect the Company.

**Oversight of Committee Matters**

1. The Committee may form and delegate authority to subcommittees when appropriate.

2. The Committee shall have authority and appropriate funds to retain, consult with and compensate outside counsel and other advisors as the Committee may deem appropriate.

3. The Committee shall conduct an annual evaluation of its performance in fulfilling its duties and responsibilities under this Charter, and shall assess the adequacy of the reporting and information provided by management to support the Committee's oversight responsibilities.

4. The Committee shall, on an annual basis, review and reassess the adequacy of this Charter and recommend any proposed changes to the Board for approval.

5. The Committee shall operate in accordance with the Regulatory, Compliance & Government Affairs Committee Operating Procedure.

B. **Regulatory, Compliance and Government Affairs Committee Operating Procedure**

1. The Company shall maintain the Regulatory, Compliance, and Government Affairs Committee ("RCGC" or the "Committee") of the Board of Directors (the "Board") for a period of at least five years.

2. The Committee shall oversee regulatory, compliance, quality, and governmental affairs matters that may impact the Company, as set forth in the Committee's Charter.

3. In support of its oversight responsibility, the Committee shall, at a minimum, receive the following in person reporting:

a. Chief Compliance Officer . At least quarterly, the Johnson & Johnson ("J&J") Chief Compliance Officer ("CCO") shall report to the RCGC regarding the global implementation, monitoring, and effectiveness of the Company's health care

compliance and privacy programs. The agenda will include reports related to matters under the purview of the CCO, exceptions reporting related to compliance policies and procedures, and discussion of significant new and ongoing regulatory investigations. At least annually, the CCO shall report on the adequacy of resource allocation to the CCO's organization. At least annually, the CCO shall report on the strategic goals and objectives of the CCO's organization. Also at least annually, the CCO shall provide a review of trends affecting the Company's regulatory compliance and, as appropriate, plans of action to respond to such trends from a preventive standpoint. The CCO will provide interim reporting directly to the Chair of the RCGC regarding substantial compliance matters.

b. J&J Chief Quality Officer . At least quarterly, the J&J Chief Quality Officer ("CQO") shall report to the RCGC regarding the global implementation, monitoring, and effectiveness of the Company's quality and compliance programs. The CQO shall report at least annually on the implementation and effectiveness of the Quality Policy and the Standards promulgated thereunder. In addition, at least annually, the CQO shall report to the Committee regarding the adequacy of resource allocation to the Company's quality systems and operations. At least annually, the CQO shall report on the strategic goals and objectives of the CQO's organization. Also at least annually, the CQO shall provide a review of trends affecting quality and compliance issues at the Company, and, as appropriate, plans of action to respond to such trends from a preventive standpoint. The CQO will provide interim reporting directly to the Chair of the RCGC regarding substantial quality and compliance matters.

c. V.P. Corporate Internal Audit . At least quarterly, the V.P. Corporate Internal Audit ("V.P. CIA") shall report to the RCGC regarding the implementation of the annual audit plan in the relevant areas, along with any material findings. At least annually, the V.P. CIA shall report on the adequacy of resources for the annual audit plan in the relevant areas. The V.P. CIA will provide interim reporting directly to the Chair of the RCGC regarding substantial matters in the relevant areas.

d. V.P. Supply Chain . At least annually, the V.P. Supply Chain shall report to the RCGC regarding supply chain risk management issues. This reporting shall include a review of trends affecting the Company's supply chain, and, as appropriate, plans of action to respond to such trends from a preventive standpoint. The V.P. Supply Chain will provide interim reporting directly to the Chair of the RCGC regarding substantial supply chain matters.

e. Other reporting . At least annually, the Committee shall receive reporting concerning medical safety and related quality issues, which will include a review of quality and safety issues impacting each Sector presented by the respective Sector Chief Quality Officer and Sector Chief Medical Officer (or equivalent). At least annually, relevant J&J officers as determined by the Committee shall report concerning the Company's Enterprise Risk Management ("ERM") program for the ERM areas under the Committee's purview, and those reports shall provide information to support the Committee's function set forth in Item 4 below. The Committee also shall receive reporting from the Corporate Vice President of Government Affairs and Policy with respect to the Company's governmental affairs strategies and priorities.

4. At least biennially, the RCGC shall consider the effectiveness of and recommended changes to the ERM program for the ERM areas under the Committee's purview. The RCGC shall communicate any recommended changes to the full Board.

5. The Committee shall be promptly notified of decisions and actions related to the appointment and/or termination of, or material compensation changes for, the V.P. Supply Chain, the J&J CCO, or the J&J CQO.

6. The CCO, CQO, V.P. Supply Chain and V.P. CIA shall have direct access to the Committee and its Chairman.

7. At least annually, the Committee shall hold a joint session with the Audit Committee to review major non-financial compliance matters at the Company.

## IV. Additional Quality Standards

### A. New PRM Standard

J&J will design and implement a Product Risk Management ("PRM") Standard under the Quality Policy and the Quality Framework. The PRM Standard will address the overall quality process for appropriate reporting, escalation, and remediation of issues arising with products (as defined in the Quality Policy). The PRM Standard will address the following topics, among others: responsibility for development of action plans; parameters for development of and adoption of resolution timelines; documentation requirements; and quality metrics for evaluating issue resolution, including tracking remediation against established timelines. The PRM Standard will set forth the independence and role of Quality personnel in the PRM process, and will provide that all quality issues subject to the PRM Standard will be managed in accordance with the escalation reporting line defined in the Quality Policy. The PRM Standard will be a mandatory standard applicable across the J&J Enterprise. Compliance with the PRM Standard will be subject to oversight by the independent Enterprise Regulatory Compliance Group and by

the J&J Quality organization. The CQO will be responsible for ensuring the design and adoption of appropriate Sector Standards and SOPs, as necessary, to implement the Enterprise PRM Standard. The PRM Standard will be implemented during 2013.

**2. Revision to Quality Policy**

Add the following text to POL-001, section 6. Management Responsibility, as item 2.c.:

> "In all matters of quality & regulatory compliance escalation, the decision making line is to the Quality & Compliance organization."

**3. New Adverse Event Management Standard**

J&J will design and implement an Enterprise-wide Adverse Event Management ("AE") Standard under the Quality Policy and the Quality Framework, which will enhance existing AE standards. The AE Standard will address the process for health authority reporting of undesirable experiences associated with the use of a regulated J&J product. The AE Standard will address the following topics, among others: responsibility for capturing and reporting adverse events; parameters for development of and adoption of reporting timelines; documentation requirements; and assuring quality metrics are in place for evaluating AE management. The AE Standard will be a mandatory standard applicable across the J&J Enterprise. Compliance with the AE Standard will be subject to oversight by the independent Enterprise Regulatory Compliance Group and by the J&J Quality organization. The CQO will be responsible for ensuring the design and adoption of appropriate Sector Standards and SOPs, as necessary, to implement the Enterprise AE Standard. The AE Standard will be implemented prior to or during 2014.

**4. New Non-Conformance Management Standard**

J&J will design and implement a Non-Conformance Management ("NC") Standard under the Quality Policy and the Quality Framework. The NC Standard will address the process for documenting and processing non-conformances in order to control and correct J&J products that do not conform to specified requirements. The NC Standard will address the following topics, among others: requirements and responsibility for identification, documentation, evaluation/investigation, segregation and disposition of non-conforming products; and assuring quality metrics are in place for evaluating the management of non-conformances. The NC Standard will be a mandatory standard applicable across the J&J Enterprise. Compliance with the NC Standard will be subject to oversight by the independent Enterprise Regulatory Compliance Group and by the J&J Quality organization. The CQO will be responsible for ensuring the design and adoption of appropriate Sector Standards and SOPs, as necessary, to implement the Enterprise NC Standard. The NC Standard will be implemented prior to or during 2014.

V. **Website Disclosure**

For a period of five (5) years, the Company shall post an annual report on J&J's internet site confirming:

a. the reporting and oversight responsibilities of the Regulatory, Compliance & Government Affairs Committee (the "Committee");

b. the number of Committee meetings with management and the participants;

c. that the Committee received reporting from management related to the organization, implementation and effectiveness of the Company's compliance and quality programs;

d. that the Committee received reporting from management regarding, inter alia, compliance and quality trends affecting the Company's regulatory compliance and compliance and quality issues at J&J, implementation and material findings of the annual audit plans, trends affecting the Company's supply chain, medical and quality issues, and Enterprise Risk Management (ERM) for ERM areas under the Committee's purview;

e. that the Committee reviewed with management significant compliance and quality matters; and

f. that the Committee reported to the full Board.

**EXHIBIT B**

**GOVERNANCE ENHANCEMENTS AND CHANGES**

As set forth below, the Company's corporate governance and compliance organizational structure, policies, protocols and procedures have been enhanced and changed since early 2010. The enhancements and changes were implemented and adopted as a consequence of internal and external considerations, including (i) the Company's continual review and evaluation of its policies, processes and procedures, (ii) the underlying conduct and government actions and investigations referenced in the Derivative Actions, (iii) the Derivative Actions, and (iv) the Special Committee investigation and findings. During the Settlement Commitment Term, the Company may make modifications that are consistent with the objectives of the Settlement to the provisions set forth in this Exhibit B.

I. **BOARD LEVEL**

A. **Board Oversight of J&J's Enterprise Risk Management (ERM) Framework** .

1. **Board Responsibility for ERM Framework** . The Board has oversight responsibility for the ERM framework (described below, see Section II.A.). The Board meets at regular intervals with key members of management, who have primary responsibility for risk management within their areas.

2. **Board Reports** . The Board also receives regular reports on aspects of the Company's risk management from senior representatives of the Company's independent auditor. The Audit Committee meets in private sessions with the Chief Finance Officer (CFO), General Counsel, J&J Chief Compliance Officer (J&J CCO), VP of Corporate Internal Audit (VP-CIA), and representatives of the independent auditor regarding aspects of risk management. The Board also met with the J&J Chief Quality Officer (J&J CQO) every quarter in 2011. Certain of this reporting will now be made to the

Regulatory, Compliance & Government Affairs Committee ("RCGC") in accordance with its Charter and Operating Procedure.

B. **Regulatory, Compliance & Government Affairs Committee**

Based upon the work of the Special Committee, the Board authorized the creation of a board committee to oversee the regulatory compliance and quality programs of the Company. In accordance with that authorization, the Board created the Regulatory, Compliance & Government Affairs Committee. The Charter and Operating Procedures for that committee were negotiated and adopted pursuant to this Settlement and are set out in Exhibit A to the Stipulation of Settlement.

II. **MANAGEMENT LEVEL**

A. **J&J's Enterprise Risk Management Framework.** J&J had previously instituted an overarching ERM framework for the entire J&J enterprise, including the business units and corporate functions.

1. **J&J's Consolidated ERM Process.** Under the ERM Framework, ERM at J&J is a consolidated process through which the Board, management, and other J&J personnel apply a common risk management approach across the enterprise, with identified ERM components, such as objective setting, risk identification and assessment, risk response and control activities, and communication and monitoring. ERM components are applied across J&J's business units and also across a number of defined risk function areas.

2. **Risk Function Leadership Teams.** Each risk function area has a leadership team.

a. Individual business units and risk function areas are responsible for performing risk assessments and audits to identify and assess trends and emerging risks, and for developing remediation plans when necessary. The effectiveness of action plans is monitored through review of metrics as part of ongoing management reviews.

b. Each business unit and each risk function area communicates identified risks and the response strategies to its leadership team, and will escalate issues as necessary and appropriate to its respective Executive Committee member, or directly to the Audit Committee or the RCGC, as appropriate.

3. **Enhancements to J&J's ERM Framework** . During the pendency of the Derivative Actions, J&J's ERM Framework has been enhanced to reflect, inter alia, the following organizational and process changes:

a. **Streamlined Escalation Procedure.** J&J has established requirements for escalation applicable to all J&J operating companies and businesses. Potential violations of law or of J&J policies are identified in multiple ways. For example, operating companies identify issues when testing and monitoring internal controls over compliance policies (such as the Foreign Corrupt Practices Act (FCPA), Quality, and Safety). Also, issues are identified through hotline calls or other reporting by employees. Pursuant to J&J's escalation policy, any covered issue must be reported within three business days to the VP-CIA. The VP-CIA acts as the focal point for receiving reports, bringing allegations to the Triage Committee for review, monitoring the timely investigation and resolution of potential violations, and reporting on such matters

to senior management, and where appropriate, to the Audit Committee. Where appropriate, the VP-CIA will make such reports to the RCGC in accordance with its Charter and Operating Procedure.

b. **Consolidated Quality and Supply Chain Functions** . J&J has implemented a company-wide plan to more effectively coordinate Quality and Supply Chain (described below), while also reducing complexity and risk.

B. **Supply Chain.**

1. **J&J Supply Chain (JJSC)** . J&J has implemented a global Supply Chain function to carry out procurement, manufacturing, and supply chain quality assurance and distribution for all of J&J's businesses. The JJSC includes a worldwide network of manufacturing sites, external manufacturers, and distribution centers. Enterprise and Sector Supply Chain leaders ensure that appropriate investments are made, ensure escalation of significant events and risks, monitor enterprise trends and establish new risk management approaches when necessary. The Vice President, J&J Supply Chain has reported to a J&J Vice Chairman in the past, and will continue to report to a direct report of the CEO. The Vice President, J&J Supply Chain will provide quarterly in-person reporting to the CEO in a private session.

The Vice President, J&J Supply Chain provides an annual report to the full Board and to the Audit Committee related to Supply Chain issues. That report will now be made to the RCGC in accordance with its Charter and Operating Procedure.

2. **Supply Chain Risk Management** . The Supply Chain Leadership Team uses dashboard metrics, risk assessments, business continuity planning exercises, and other inputs to identify patterns and trends, and highlight risks for follow-up actions.

Risk management is primarily the responsibility of the business units, with shared responsibility with JJSC for oversight and risk mitigation. Critical metrics are reported to the Supply Chain Leadership Team, to the management Compliance Committee, or to the appropriate Board committee. Reporting formerly made to the Audit Committee will now be made to the RCGC in accordance with its Charter and Operating Procedure.

C. **Quality.**

1. **Single Framework for Quality and Compliance.** A key aspect of the new J&J Supply Chain operating model is the creation of a single framework for Quality & Compliance across all of J&J's operating companies. This single framework is intended to standardize processes in the Company's quality systems and provide greater oversight in order to reduce both complexity and risk in the area of quality.

2. **The J&J Chief Quality Officer (J&J CQO).** The J&J CQO reports to the Vice President, Supply Chain, and makes quarterly reports to the Audit Committee or the Board. The J&J CQO will now make such reports to the RCGC in accordance with its Charter and Operating Procedure.

3. **J&J CQO Responsibilities** . The J&J CQO has oversight of quality throughout the Enterprise.

a. All staff in Quality and Regulatory Compliance functions worldwide have a reporting relationship to the J&J CQO.

b. The J&J CQO sets Enterprise Quality Policy and Standards to promote consistency and uniformity in quality requirements.

c. The J&J CQO reports quality and regulatory compliance metrics and issues to Executive Management.

d. The J&J CQO has established and will maintain an Enterprise Regulatory Compliance function to provide independent oversight of the effectiveness of J&J's Quality systems.

4. **Sector CQO Responsibilities** . J&J has appointed Chief Quality Officers for each business Sector. Sector CQOs report to the J&J CQO.

a. Sector CQOs are responsible for governance of quality and regulatory compliance activities at R&D companies, marketing and local operating companies, and JJSC manufacturing sites.

b. Sector CQOs are responsible to implement and oversee a Quality and Regulatory Compliance strategy.

c. Sector CQOs are required to establish a Regulatory Compliance function to provide independent oversight of the effectiveness of the Sector's Quality systems. This Sector oversight program is independent of the Enterprise oversight program.

d. Sector CQOs are required to communicate risks to the Sector management and to the J&J CQO as appropriate.

5. **The J&J Quality Policy** . The J&J Quality Policy is the top-level Quality document and defines Quality & Compliance requirements throughout the enterprise. The current version of the Quality Policy is POL-001, issued on March 31, 2011. The Quality Policy requires, among other things, that every J&J company establish an independent quality function with the necessary resources, establish an internal audit program for its quality system, establish a comprehensive system for handling product complaints and reporting adverse events, document the process for investigating and

controlling nonconformities, establish procedures for the conduct of field action activities, and establish processes for corrective actions and preventive actions.

6. **J&J Standards** . J&J Standards set specific requirements in quality and technical areas that are uniform throughout the Enterprise. J&J Standards are mandatory and applicable to every J&J company. Sector Standards promulgated pursuant to J&J Standards must be consistent with those J&J Standards. Individual J&J sites align procedures where needed to assure consistency with J&J and Sector Standards. The following new enterprise-wide quality Standards have been implemented at the Company in 2011:

a. Management Review (STD-001), implemented on June 30, 2011, sets requirements for management review processes at company, Sector, and Enterprise levels, identifies who needs to be present at management reviews and what needs to be reviewed, and includes review of metrics in a number of areas.

b. Escalation of Quality and Regulatory Compliance Issues (STD-002), implemented on June 30, 2011, sets requirements for processes at every J&J company to escalate information on quality issues to the appropriate management level. These requirements are to ensure that information on all significant quality and regulatory compliance issues is escalated in a timely manner, including the escalation of certain types of issues to identified persons within one business day.

c. Field Action (STD-003), implemented on June 30, 2011, requires every J&J company to establish field action procedures. A field action is any correction, corrective action, or preventive action that is implemented with respect to a product that has left J&J's control, i.e., actions such as alerts to healthcare

providers and recalls. The Field Action Standard establishes parameters for Quality Review Board proceedings throughout J&J. Specifically, pursuant to the Field Action Standard, a formally constituted Quality Review Board must evaluate product quality issues in the field and determine whether field action (removal or field correction) is required, and the scope and depth of that action.

d. Pallet Management (STD-005), implemented on September 1, 2011, has the purpose of preventing pallets from adversely impacting the quality of the materials and products that are stored on them, and provides for the elimination of wood pallets in a number of applications by June 2012.

e. Additional enterprise-wide Quality Standards are being developed in 2012, including related to Corrective and Preventive Action (CAPA), Training, and Procurement Controls/Supplier Quality.

7. **Additional Risk Management Provisions** . J&J has implemented a coordinated mandatory two-tier audit program between Enterprise and Sector. These two groups work in a coordinated fashion, to assess compliance from a top-down and a bottom-up approach. Regulatory outreach and intelligence teams are established for emerging trends. Enterprise oversight is maintained by an Enterprise Regulatory Compliance Group that reports directly to the J&J CQO. This group has been realigned and expanded to improve regulatory compliance of operating companies by providing robust, mandatory independent assessments.

a. The Enterprise Regulatory Compliance Group's independent audit program will evaluate, on a three-year cycle, all of J&J's internal manufacturing plants, operating companies with regulated quality activities, and distribution

centers that are inspected by health authorities. Higher risk sites will be audited more frequently.

b. The audit program, commenced in 2011, is designed to audit more than 100 sites in any given year going forward.

c. Significant issues are escalated and reported via metrics. Significant inspections will have independent review of responses and follow-up.

d. The Enterprise Regulatory Compliance Group reports directly to the J&J CQO, who is outside of the business units and the Sectors, assuring independent oversight of Quality and Regulatory Compliance at J&J, apart from Sector or Supply Chain Quality & Compliance activities.

e. Pursuant to SOP-027, effective June 21, 2011, J&J established a group within the Enterprise Regulatory Compliance function to provide independent oversight by corporate-level management of McNeil's activities under the Consent Decree of Permanent Injunction with the U.S. FDA for manufacturing facilities operated by the McNeil Consumer Healthcare Division of McNeil-PPC, Inc. in Las Piedras, PR, Fort Washington, PA, and Lancaster, PA.

D. **Health Care Compliance.**

1. **Health Care Compliance and Privacy (HCC&P)** . J&J's integrated, enterprise-wide HCC&P organization is responsible for issues related to the FCPA and other anti-corruption laws and regulations, False Claims Act, Anti-Kickback Statute, and off-label promotion, as well as the implementation of corporate integrity and deferred prosecution agreements. The HCC&P organization is responsible for providing

infrastructure and guidance to effectively prevent and/or detect violations of law, regulations, policies, and codes of conduct.

2. **The J&J Chief Compliance Officer (J&J CCO).** The J&J CCO reported to a J&J Vice Chairman in the past, and will continue to report to a direct report of the CEO. The J&J CCO will provide quarterly in-person reporting to the CEO in a private session. The J&J CCO made quarterly reports to the Audit Committee. The J&J CCO will now make such reports to the RCGC Committee in accordance with its Charter and Operating Procedure.

3. **Sector Health Care Compliance (HCC) Officers.** HCC Officers are appointed for each Sector and for geographic regions. Within the Sectors, there are HCC Officers embedded in each of the business units. All of the HCC Officers report through the independent HCC&P organization, not through the business units. Compliance issues are regularly reported at operating company management board meetings and at the Sector management level.

4. **HCC Risk Management** . HCC&P uses a number of tools as compliance indicators, including risk assessments, business profiles, ongoing testing and monitoring, hotline metrics, and the results of audits performed by Corporate Internal Audit. HCC&P conducts testing and monitoring at the business units in accordance with a risk-based testing plan.

a. The J&J CCO chairs the Triage Committee, which has membership from Corporate Internal Audit, the Law Department, Global Security and Human Resources. Twice weekly, the Triage Committee reviews sensitive issue allegations and the progress of related investigations.

b. Key risk and compliance issues are reported to the management Compliance Committee, Executive Committee, and Audit Committee on an ongoing basis by the J&J CCO, at regular intervals or as needed. The J&J CCO will now report such issues to the RCGC in accordance with its Charter and Operating Procedure.

c. In connection with the reorganization of HCC, the management Compliance Committee expanded and clarified its mission:

i. The Compliance Committee is composed of the J&J CCO, the Integration Leader, the Sector HCC Officers, VP-CIA, the Corporate Secretary, the J&J CQO, and representatives from the Law Department, Human Resources, and Finance.

ii. The responsibilities of the Compliance Committee include, inter alia: (1) to facilitate the exchange of expertise and knowledge among the represented Compliance functions; (2) to review and provide input into reports to the Sector management, Executive Committee, Audit Committee, going forward the RCGC, and the Board; (3) to escalate Compliance issues to the relevant management or governing body; (4) to review and discuss emerging Compliance concerns and recommend actions; and (5) to provide input into J&J's Enterprise Risk Management.

iii. The Compliance Committee has quarterly meetings in preparation for Sector management, Executive Committee, Audit Committee meetings, and going forward the RCGC meetings.